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Original Research

Age-dependent changes in the risk of weight gain in Chinese adults: results from the Kailuan cohort study

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ABSTRACT

Objectives: Over the past decades, China has seen a dramatic epidemic of overweight and obesity. However, the optimal period for interventions to prevent overweight/obesity in adulthood remains unclear, and little is known regarding the joint effect of sociodemographic factors on weight gain. We aimed to investigate the associations of weight gain with sociodemographic factors, including age, sex, educational level, and income.

Study design: This was a longitudinal cohort study.

Methods: This study included 121,865 participants aged 18–74 years from the Kailuan study who attended health examinations over the period 2006–2019. Multivariate logistic regression and restricted cubic spline were used to evaluate the associations of sociodemographic factors with body mass index (BMI) category transitions over two, six, and 10 years.

Results: In the analysis of 10-year BMI changes, the youngest age group had the highest risks of shifting to higher BMI categories, with odds ratio of 2.42 (95% confidence interval 2.12–2.77) for a transition from underweight or normal weight to overweight or obesity and 2.85 (95% confidence interval 2.17–3.75) for a transition from overweight to obesity. Compared with baseline age, education level was less related to these changes, whereas gender and income were not significantly associated with these transitions. Restricted cubic spline analyses suggested reverse J-shaped associations of age with these transitions.

Conclusions: The risk of weight gain in Chinese adults is age dependent, and clear public healthcare messaging is needed for young adults who are at the highest risk of weight gain.

Introduction

Overweight and obesity have become a major global public health problem,[1,2] with more than 1.9 billion adults having overweight and more than 650 million adults having obesity worldwide in 2016.[3] Between 1975 and 2016, the global prevalence of obesity in adults increased from 3% to 11% in men and from 6% to 15% in women.[4] Alongside the rapid economic and demographic shifts that have occurred in China, the prevalence of obesity has been increasing, rising from 3.1% in 2004 to 8.1% in 2018.[5,6] It is predicted that the prevalence of overweight/obesity in Chinese adults will reach 65.3% by 2030.[7] Obesity is a recognized risk factor for major non-communicable diseases,[8] including cardiovascular disease, diabetes, and cancer,[9,10] and is also associated with higher risks of osteoarthritis, sleep apnea, kidney disease, hepatobiliary disease, and depression.[11,12] This emphasizes the importance of identifying and modifying the factors that determine the onset and progression of overweight and obesity.

A large number of studies have shown that the risk factors for overweight and obesity include an unhealthy diet, physical inactivity, certain medications, and inadequate sleep, which interact

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with genetic susceptibility to cause weight gain and ultimately lead to overweight and obesity.[13–15] However, the critical period for controlling risk factors for overweight and obesity in adulthood remains unclear. Although preliminary observations suggest that young adults are at a higher risk of weight gain than older people,[16] available evidence is lacking from Asian countries accounting for the majority of the global population. In addition, there have been no large-scale cohort studies analyzing the associations of weight gain with age and other important sociodemographic characteristics in China.

In the present study, we used longitudinal data from a large population-based cohort study to examine the joint effect of age, sex, educational level, and income on the risk of weight gain in China.

Material and methods

Study population

The Kailuan study is an ongoing community-based prospective cohort study in Tangshan, China. The detailed study design and procedures have been described previously.[17,18] From 2006 to 2007, employees of the Kailuan Group were recruited to participate in comprehensive biennial health examination at 11 hospitals affiliated with the Kailuan Group. Data were obtained by questionnaire interview, physical examination, and laboratory tests. Participants were eligible for inclusion in this study if they attended at least two health examinations in Kailuan between 2006 and 2019. The exclusion criteria were a diagnosis of pregnancy or viral hepatitis during the follow-up period, age ≥75 years, and missing body mass index (BMI) values at the beginning or end of all three follow-up intervals.

The Ethics Committee of Kailuan Hospital approved this cohort study, and written informed consent was provided by all the participants.

Assessment of sociodemographic variables

Sociodemographic characteristics used in these analyses, including age, sex, family monthly income, and educational level, were obtained using data from the questionnaires at each health examination. We regarded the time at which each participant first attended for a medical examination as the baseline, and according to the ages of the participants at baseline, they were placed into six age groups: 18–24, 25–34, 35–44, 45–54, 55–64, and 65–74 years. With respect to socio-economic status, the educational level of the participants was categorized as primary or below, secondary, or tertiary or above; and family monthly income was categorized as <¥1000, ¥1000–¥3000, or >¥3000.

Assessment of BMI status

For each participant, height and body weight are measured by trained medical staff according to standardized methods. The measurements of height and body mass were made to precisions of 0.1 cm and 0.1 kg, respectively. BMI was calculated as body weight (kilogram) divided by height (meter) squared. The classification of BMI was based on the World Health Organization guidelines (underweight, BMI <18.5 kg/m^2; normal weight, BMI 18.5–24.9 kg/m^2; overweight, BMI 25.0–29.9 kg/m^2; and obesity, BMI ≥30 kg/m^2).[19] We used the baseline BMI and the BMI measurements made at subsequent visits two, six, and 10 years after initial physical examination for the assessment of transitions between BMI categories.

Assessment of covariates

Data regarding covariates were collected using questionnaires and laboratory tests at a health examination and updated every two years. These included smoking status, alcohol consumption status, physical activity, the use of antidiabetic drugs or diuretics, self-reported medical history (of hypertension, diabetes, atherosclerotic cardiovascular disease [ASCVD], chronic kidney disease, and cancer), and total serum cholesterol and triglyceride concentrations. Participants who currently smoked (smoked cigarettes in the past 30 days) or with a history of smoking (smoked ≥100 cigarettes in lifetime) were defined as smokers (i.e. ever-smokers), and those who currently drank (alcohol consumption at least three times per week and more than one cup of alcohol each time during the last month) or who had a history of drinking (alcohol consumption a month ago) were defined as drinkers (i.e. ever-drinkers).[20] Physical activity was defined using a frequency of exercise of more than three times a week, with a duration of >30 min on each occasion. ASCVD was defined using a history of myocardial infarction or stroke. Participants were evaluated after an eight hour fast using calibrated equipment, and the total cholesterol and triglyceride concentrations were measured using an automated analyzer (Hitachi 747, Hitachi, Tokyo, Japan).

Statistical analysis

We summarized baseline characteristics of the participants by follow-up interval and presented them as mean (standard deviation) or median (interquartile range) for continuous variables and number (percentage) for categorical variables. While the longitudinal transitions of BMI status are diverse, the focus of our study is on the onset and progression of overweight and obesity, diseases with shared pathophysiology and adverse long-term clinical consequences. Thus, two unhealthy BMI transition statuses in each time interval were examined in our study: transition from underweight or normal weight to overweight or obesity and transition from overweight to obesity. We used multivariate logistic regression models to calculate odds ratios (ORs) and corresponding 95% confidence intervals (CIs) for the relationships of age and other sociodemographic factors (sex, educational level, and income) with transition to higher BMI categories over two year, six year, and 10 year periods, with adjustment for the potential confounders. In addition to mutual adjustments for sociodemographic factors, the covariates that were also included in the model were baseline BMI, smoking status, drinking status, physical activity, myocardial infarction, stroke, hypertension, diabetes, chronic kidney disease, cancer, the use of diuretics and antidiabetic drugs, and the total cholesterol and triglyceride concentrations. To further illustrate the correlation between age and BMI status transitions in the three time intervals, we also used a restricted cubic spline with four knots located at the 5th, 35th, 65th, and 95th percentiles to flexibly model the possible non-linear relation. The maximum age was chosen as a reference.

Moreover, we performed subgroup analyses according to smoking status (smoker vs non-smoker), drinking status (drinker vs non-drinker), and physical activity (physical activity vs physical inactivity). To assess the robustness of our findings, we performed a series of sensitivity analyses. First, we did a complementary analysis using classification of BMI based on the Chinese criteria (underweight, BMI <18.5 kg/m^2; normal weight, BMI 18.5–23.9 kg/m^2; overweight, BMI 24.0–27.9 kg/m^2; obesity, BMI ≥28 kg/m^2).[21] Second, we excluded individuals with ASCVD at baseline. Third, we excluded individuals with diabetes or hypertension at baseline. Fourth, we excluded individuals with chronic kidney disease at baseline. Fifth, we excluded individuals with cancer. Sixth, to maximize statistical power and minimize bias that might occur if

participants who attend only one health examination were excluded from analyses, we repeated our analyses with the data sets with imputed variables from multiple imputation by chained equations. Finally, we also conducted a sensitivity analysis without excluding participants aged ≥75 years. Data analyses were conducted using SAS software (version 9.4, SAS Institute, Cary, NC, USA). Two-sided statistical testing was performed, and $P < 0.05$ was considered to represent statistical significance.

Results

Participant characteristics

Of the 132,540 participants who attended at least two health examinations in Kailuan between 2006 and 2019, a total of 121,865 individuals of age 18–74 years were finally included in the study (Fig. 1). The demographic and clinical characteristics of participants are presented in Table 1. Participants for whom an assessment of the change in BMI status over 10 years could be made had a mean (standard deviation) age of 48.30 (11.42) years, and there was a higher proportion of men (61,891 [82.40%]) than women (13,216 [17.60%]). The mean (standard deviation) BMI of the participants was 24.92 (3.35) kg/m^2. Most of them had secondary education (63,308 [84.29%]), 30,656 (40.82%) had hypertension, and 5999 (7.99%) had diabetes.

Sociodemographic factors and the BMI status transitions

In multivariate logistic regression analyses, we found that the transition to higher BMI categories was most strongly associated with age (Fig. 2). Young participants aged 18–24 years were at the highest risk of transitioning to the higher BMI categories. Over the 10-year follow-up period, the adjusted OR for the transition from the underweight or normal weight to the overweight or obesity in the youngest group (18–24 years) was 2.42 (95% CI, 2.12–2.77) in comparison with individuals aged 65–74 years. The absolute risk of the transition from the underweight or normal weight BMI category to the overweight or obesity BMI category increased from 21.16% for the 65–74 years age group to 40.62% for the 18–24 years age group. In addition, we observed the weak obesity-depressing

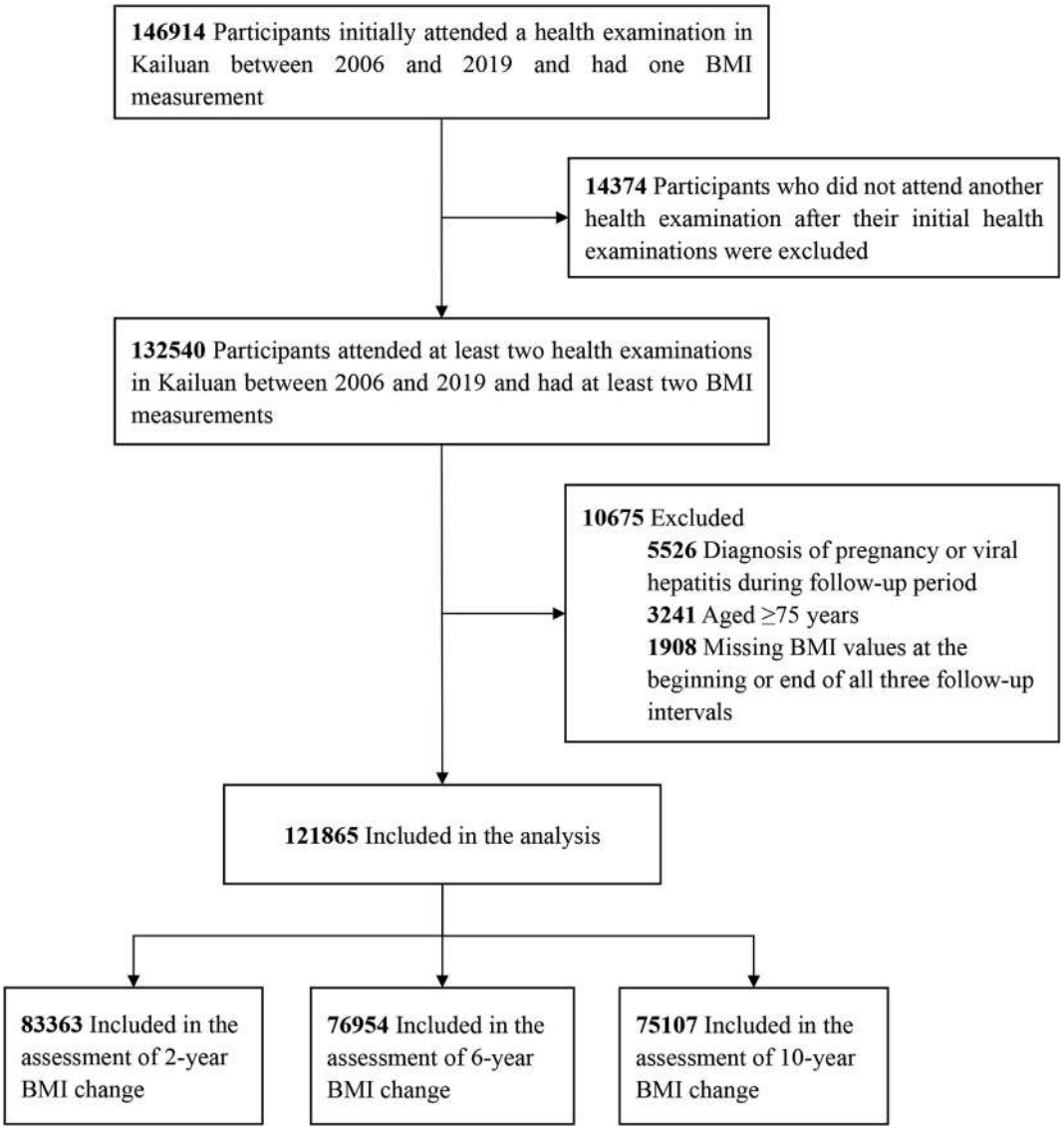

Fig. 1. Flowchart of enrollment of participants in this study. We regarded the time at which each participant first attended for a medical examination as the baseline and respectively included individuals with follow-up intervals of 2, 6, and 10 years since their initial medical examinations.

Table 1
Characteristics of the participants at baseline.

Characteristics	2-year BMI change (n = 83,363)	6-year BMI change (n = 76,954)	10-year BMI change (n = 75,107)
Age (years)	46.73 (12.12)	47.25 (11.95)	48.30 (11.42)
18–24	3882 (4.66)	3299 (4.29)	2612 (3.48)
25–34	11,462 (13.75)	9739 (12.66)	7764 (10.34)
35–44	20,034 (24.03)	18,431 (23.95)	16,617 (22.12)
45–54	27,441 (32.92)	24,713 (32.11)	26,425 (35.18)
55–64	14,718 (17.66)	15,677 (20.37)	16,808 (22.38)
65–74	5826 (6.99)	5095 (6.62)	4881 (6.50)
Sex			
Female	12,642 (15.17)	12,581 (16.35)	13,216 (17.60)
Male	70,721 (84.83)	64,373 (83.65)	61,891 (82.40)
BMI (kg/m^2)	24.85 (3.36)	24.91 (3.36)	24.92 (3.35)
<18.5	2019.0 (2.42)	1785.0 (2.32)	1688.0 (2.25)
18.5–24.9	42,222 (50.65)	38,550 (50.09)	37,517 (49.95)
25.0–29.9	33,452 (40.13)	31,186 (40.53)	30,639 (40.79)
≥30.0	5670.0 (6.80)	5433.0 (7.06)	5263.0 (7.01)
Education level			
Primary or below	5690 (6.83)	5856 (7.61)	5925 (7.89)
Secondary	69,364 (83.21)	64,606 (83.95)	63,308 (84.29)
Tertiary or above	8309 (9.97)	6492 (8.44)	5874 (7.82)
Family monthly income, ¥			
<1000	21,204 (25.44)	18,738 (24.35)	19,013 (25.31)
1000–3000	40,226 (48.25)	37,908 (49.26)	36,398 (48.46)
>3000	21,933 (26.31)	20,308 (26.39)	19,696 (26.22)
Lifestyle			
Smoke	33,239 (39.87)	29,568 (38.42)	28,311 (37.69)
Drink	34,859 (41.82)	31,707 (41.20)	30,764 (40.96)
Physical activity	12,225 (14.66)	11,659 (15.15)	11,515 (15.33)
Prevalence of chronic diseases			
Myocardial infarction	655 (0.79)	684 (0.89)	683 (0.91)
Stroke	997 (1.20)	936 (1.22)	875 (1.17)
Hypertension	32,415 (38.88)	30,874 (40.12)	30,656 (40.82)
Diabetes	6734 (8.08)	6069 (7.89)	5999 (7.99)
Chronic kidney disease	83,444 (10.13)	8977 (11.67)	8952 (11.92)
Cancer	227 (0.27)	199 (0.26)	213 (0.28)
Antidiabetic drugs	1607 (1.93)	1546 (2.01)	1509 (2.01)
Diuretics	676 (0.81)	659 (0.86)	721 (0.96)
TC (mmol/L)	4.89 (1.11)	4.91 (1.12)	4.93 (1.12)
TG (mmol/L)	1.27 (0.87–1.94)	1.27 (0.89–1.94)	1.28 (0.90–1.95)

BMI, body mass index; TC, total cholesterol; TG, triglyceride.
Data are presented as mean (standard deviation), median (interquartile range), or n (%).

effect of education. Education level (most educated vs least educated OR, 0.75; 95% CI, 0.66–0.84) was less associated with this transition. However, sex (men vs women OR, 1.05; 95% CI, 0.98–1.12) and income (most affluent vs least affluent OR, 0.99; 95% CI, 0.93–1.05) were not significantly associated with this change.

In terms of the progression from overweight to obesity, the adjusted OR for the transition from the overweight to the obesity in the youngest group (18–24 years) was 2.85 (95% CI, 2.17–3.75) compared with the 65–74 years age group. The absolute risk of the transition from the overweight to the obesity category increased from 6.22% for the 65–74 years age group to 21.34% for the 18–24 years age group. As expected, the age-related patterns to the transition to higher BMI categories over two and six years were broadly similar to that identified over 10 years, except for the transition from the underweight or normal weight to the overweight or obesity category over two years (Supplementary Table S1 and Table S2). Furthermore, the restricted cubic spline model showed a reverse J-shaped or U-shaped dose–response relationship between age and the risk of the transition to higher BMI categories across the three time intervals (all P-non-linearity <0.001; Fig. 3, Supplementary Figure S1 and Figure S2).

Subgroup and sensitivity analysis

The subgroup analyses performed according to smoking status, drinking status, and physical activity generated similar results to the main analysis (Supplementary Table S3–Table S5). Sensitivity analyses showed no substantial changes in the findings. Compared with our main model, similar results were obtained when BMI was classified according to the Chinese criteria (Supplementary Table S6). In addition, the estimated associations did not alter dramatically when individuals with several chronic diseases were excluded separately (Supplementary Table S7–Table S10). The results were generally consistent with the main analysis when the missing data were imputed using multiple imputation by chained equations (Supplementary Table S11). The inclusion of participants aged ≥75 years did not significantly alter the results (Supplementary Table S12).

Discussion

In the longitudinal cohort study of Chinese adults, we found age-dependent changes in the risk of weight gain and the youngest adults (aged 18–24 years) had the highest relative and absolute risk of shifting to higher BMI categories. Compared with age, education level was less related to these transitions, whereas sex and income were not significantly associated with these changes. Therefore, community and healthcare strategies for the prevention and management of overweight and obesity should target young adults who are at the highest risk of weight gain.

The association between demographic factors and weight change has been extensively researched in several cohort studies. Consistent with our findings, other previous studies have also

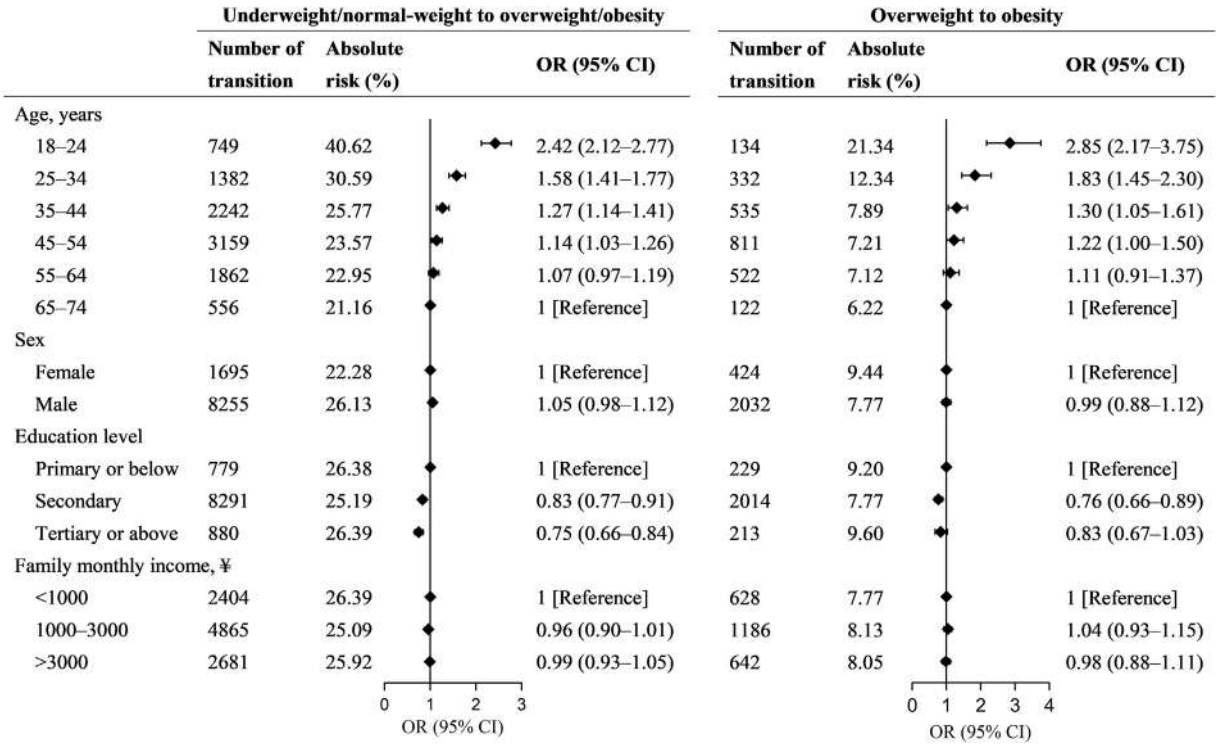

Fig. 2. Absolute risks and odds ratios of shifting to higher BMI categories over 10 years. Odds ratios were additionally adjusted for baseline BMI, smoking status, drinking status, physical activity, myocardial infarction, stroke, hypertension, diabetes, chronic kidney disease, cancer, the use of diuretics and antidiabetic drugs, total cholesterol, and triglycerides. BMI, body mass index.

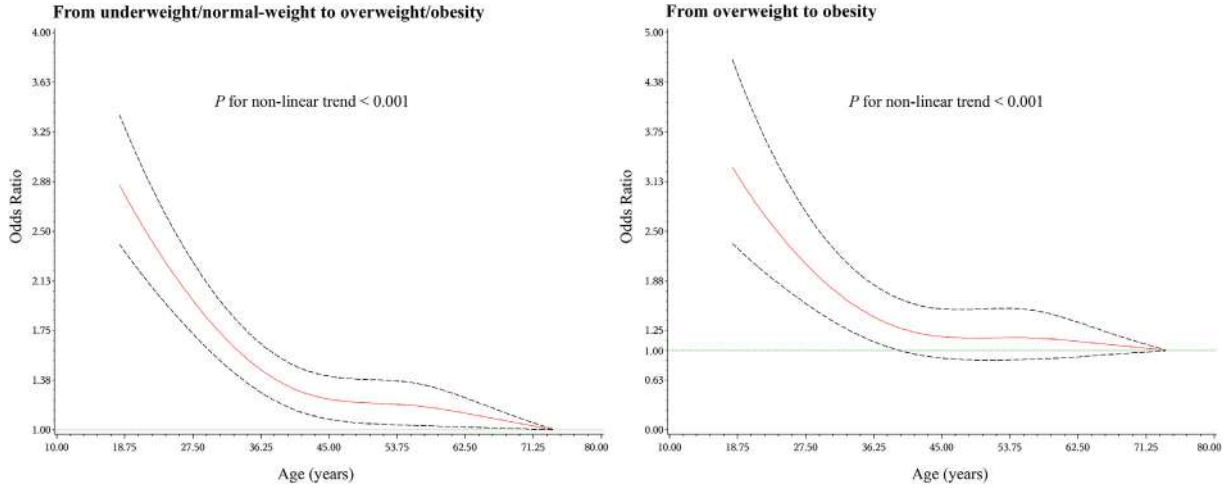

Fig. 3. Restricted cubic spline of the association between age and BMI status transition over 10 years. Solid lines indicate odds ratios, and dashed lines indicate 95% CIs from restricted cubic spline regression. The association was adjusted for gender, educational level, income, baseline BMI, smoking status, drinking status, physical activity, myocardial infarction, stroke, hypertension, diabetes, chronic kidney disease, cancer, the use of diuretics and antidiabetic drugs, total cholesterol, and triglycerides. The maximum age (74 years) was chosen as a reference. CI, confidence interval.

shown that young people are at a higher risk of weight gain than older people. An epidemiological study of the US CARDIA cohort revealed that weight gain is greatest among people in their 20s.[22] Caman et al.[23] showed in a Swedish cohort that the increase in BMI with increasing age is higher in younger individuals than in older individuals. A longitudinal study of an Austrian cohort by Peter et al.[24] showed that body weight increases between 20 and 70 years of age, with the largest increase occurring in men aged 20–25 years. However, most of these previous studies that focused on only one or a limited number of sociodemographic factors did not involve the collection of information necessary to assess several risk factors or use self-reported weight which is associated with the risks of reporting or recall bias. The present study, conducted in a large Chinese population–based cohort and involving long-term follow-up, has the strength that numerous accurate and reliable BMI measurements were made, and this has extended previous findings by evaluating the joint effect of four significant socio-demographic factors (age, sex, educational level, and income) on the change in BMI category.

The population-based longitudinal study conducted in the United Kingdom, similar in design to the present study, has reported similar findings.[16] However, we did not identify evident

associations between age and the transition from underweight or normal weight to the overweight or obesity category over the two year follow-up period. This may be attributed to the short-term changes in weight being more susceptible to multiple factors.[13] Additional studies are warranted to better elucidate the short-term effects of age on weight gain in Chinese population. Although the magnitude of the decrease in OR associated with weight gain with increasing age appears to differ according to discrepancies in geographical region and demographic characteristics of study population, both the present study and the UK study have demonstrated that young adults are at the highest risk of weight gain, which emphasizes that future prevention strategies for overweight and obesity should focus on young adults.

The mechanisms underlying the higher risk of weight gain in young adults remain unclear, but there are several possible explanations. First, at the population level, obesity is primarily driven by environmental effects that diminish the ability of people to make decisions regarding their own behavior.[25] Young adults confront unique challenges in their living environment, and numerous beverage and fast-food companies target young people, increasing their access to high-calorie foods.[26] In contrast, older people may follow more traditional lifestyles and have higher dietary fiber consumption. In addition to the physical environment, interpersonal relationships have an impact on the weight status of young adults and their willingness to lose weight.[27] Young adults with overweight or obesity tend to have more overweight friends, relatives, and romantic partners than their peers who are not overweight.[28] When living in these obesogenic environments, it may be challenging to maintain a healthy weight. Furthermore, at the individual level, a poor lifestyle with respect to diet and physical activity contributes to weight gain in an increasing number of individuals. Most young people have unhealthy dietary habits, including substantial consumption of fast food and sugary drinks and more frequent binge eating.[29–31] In addition, physical inactivity by young people because of a lack of time, motivation, and social support would further increase this weight gain.[32–34]

The findings of the present study have important clinical and public health implications. Data obtained during the Global Burden of Overweight and Obesity Study show that the prevalence of overweight and obesity is lower in young people than in older adults, but that weight gain is most rapid in those aged 20–40 years.[35] Our findings also show that the risk of weight gain is higher in young people than in older people. Thus, most adults are at high risk for overweight and obesity in early adulthood (18–44 years) rather than in late adulthood. Clinical studies have shown that the use of various weight loss interventions, including lifestyle interventions, medication, and bariatric surgery, are associated with huge challenges to the maintenance of this weight loss over time, despite good short-term outcomes.[36–38] Therefore, the prevention of obesity is particularly important in early adulthood before the onset of obesity. Moreover, weight gain between early and mid-adulthood is associated with higher risks of morbidity and mortality related to several chronic diseases in later life, including type 2 diabetes, cardiovascular disease, cancer, and non-traumatic death.[39,40] Our findings advocate for efforts to prevent overweight and obesity to extend to younger people to reduce the lifetime risk for developing major non-communicable diseases.

This study has several limitations. First, although many potential confounders were adjusted for in our analysis, we were unable to directly adjust for psychological disorders because those important covariates were not available in the Kailuan study. These and other unmeasured factors may cause residual confounding. Second, an additional limitation was the lack of consideration of dietary patterns. However, many obesogenic drivers could have distal effects on obesity.[41] For example, income inequality and chronic diseases might convert to higher obesity prevalence through a number of pathways, such as through changes in dietary patterns and psychosocial effects. Hence, dietary patterns might be mediators rather than confounders of age-dependent changes in BMI increase, which merit further study. Finally, the participants were all employees and retirees of the Kailuan Group and were mostly male. The homogeneity of geographical region and ethnicity may help minimize confounding and enhance the internal validity, but this would limit the generalizability of the findings.

Conclusions

The risk of weight gain in Chinese adults is age dependent. Young adults were found to be at significantly higher risk of weight gain than older age groups. Early adulthood may be the optimal timing for overweight and obesity prevention interventions. These findings underscore the importance of providing young adults with clear public health information because they may underestimate their risk of weight gain and imply that young adults should adhere to obesity prevention strategies and individual weight management interventions.

Author statements

Acknowledgments

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Ethical approval

The Ethics Committee of Kailuan Hospital approved this cohort study, and written informed consent was provided by all the participants. This study was conducted in accordance with Helsinki Principles. Data obtained from all participants were kept confidential.

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Competing interests

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2023.03.004.

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Themed Paper — Short Communication

An intra-action review conducted by the CDC Foundation during COVID-19 to evaluate emergency response procedures

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ABSTRACT

Objectives: During times of emergency response, the CDC Foundation leverages partnerships and relationships to better understand the situation and respond rapidly to save lives. As the COVID-19 pandemic began to unfold, an opportunity became clear to improve our work in emergency response through documentation of lessons learned and incorporating them into best practices.
Study design: This was a mixed methods study.
Methods: The CDC Foundation Response, Crisis and Preparedness Unit conducted an internal evaluation via an intra-action review to evaluate and rapidly improve emergency response activities to provide effective and efficient response-related program management.
Results: The processes developed during the COVID-19 response to conduct timely and actionable reviews of the CDC Foundation's operations led to the identification of gaps in the work and management processes and to creation of subsequent actions to address these issues. Such solutions include surge hiring, establishing standard operating procedures for processes not yet documented, and creating tools and templates to streamline emergency response operations.
Conclusions: The creation of manuals and handbooks, intra-action reviews, and impact sharing for emergency response projects led to actionable items meant to improve processes and procedures and the ability of the Response, Crisis and Preparedness Unit to quickly mobilize resources directed toward saving lives. These products are now open-source resources that can be used by other organizations to improve their own emergency response management systems.

Introduction

The CDC Foundation activated its Emergency Response Fund in January 2020 for the COVID-19 response. The magnitude of the response strained existing processes, revealing gaps in emergency response operations. This led to an intra-action review involving members of the CDC Foundation's Response Crisis and Preparedness Unit (RCPU). The review included internal evaluation of response activities to address identified barriers and gaps. Through this process, actionable items were documented, and improvements were made in emergency response operations. Sharing response-focused guidance and intra-action review results can help the CDC Foundation and other organizations improve their future engagement in emergency responses.

Background

The CDC Foundation is the sole entity authorized by Congress to mobilize resources to leverage the work of the Centers for Disease Control and Prevention (CDC). During an emergency response, the CDC may request that the CDC Foundation activate the Emergency Response Fund. Once activated, the CDC Foundation uses the Emergency Response Fund to support requests for assistance received from CDC and other implementing partners. During an emergency response, the CDC Foundation works with CDC's Emergency Operations Center leadership to understand priority response needs, gaps to filling needs and how partners can support these efforts. CDC Foundation receives resources from philanthropic, private donors, and grants from CDC to provide CDC and implementing partners with resources to fill immediate needs during public health emergencies.

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CDC Foundation's implementing partners include public and private organizations, such as non-profits, community-based organizations, and public health and academic entities. Following emergency activation, The CDC Foundation receives requests for support from key public health partners to address emergency response issues. CDC Foundation then deploys resources to address these identified priorities. As an independent non-profit, the CDC Foundation can also distribute resources to other entities (e.g. health departments, research partners) as part of the organization's own strategic initiatives.

There are multiple CDC Foundation teams that work together to mobilize resources and implement programmatic responses. The RCPU has primary responsibility for emergency response activities by establishing and overseeing partner projects through grants and contracts. As the response continued beyond activation into January 2020, the RCPU began to implement hundreds of projects with a wide range of partners, including mass hiring of public health workers to build the public health infrastructure, providing laboratory and personal protective equipment, supporting health departments and community-based organizations through grant funding, and filling additional gaps in the pandemic response. The enormity of the COVID-19 response revealed that the RCPU's effectiveness could benefit from an internal review, so an intra-action review was conducted to evaluate emergency response activities, and based on those results, RCPU rapidly adjusted activities to provide a more effective response-related program management.

Methods

An intra-action review is a method of identifying current challenges and understanding successes. The purpose of an intra-action review is to quickly address questions about current activities, emerging issues, lessons learned from gaps and challenges, and proposed changes to ensure continued success.[1] During this process, a root-cause analysis was conducted to propose practical ways to remediate identified challenges.

To conduct the intra-action review, a survey was distributed to all employees within the RCPU. The survey was conducted in September 2020, eight months into the COVID-19 response, which resulted in nine respondents from RCPU staff (response rate of 100%). This survey was distributed for the second time 15 months into the response in June of 2021, which resulted in 17 responses from RCPU staff (response rate of 27.9%). The shift in response rates is reflected by the growth of the RCPU to meet the needs of the emergency response. Note that response rates are low for the second survey, as the RCPU was actively engaging in emergency response activities, and this is an exclusively internal evaluation among a small, exclusive team. The timing of survey distribution was determined by staff capacity and status of emergency response activities, as at the time the CDC Foundation was activated for the COVID-19 response. A qualitative analysis of survey results was conducted with the lens of evaluating strengths, weaknesses, opportunities, and threats to the unit's operational capacity. The results describe the culmination of these two reports.

Results

Each response was categorized into the following themes: staffing, processes, data systems, communications, and next steps (Table 1). During the COVID-19 response, hiring surge staff—including program managers and field employees—assisted core staff in remaining focused on their primary responsibilities. New staff were brought onto the unit to increase capacity, which required efforts to refine the onboarding experience for quick resource mobilization. Confusion in onboarding processes led to delays in programmatic implementation, which needed to be addressed for the rapid implementation of projects. In response, standard operating procedures (SOPs) were created to guide the hiring of surge staff, including creation of onboarding handbooks and training videos to streamline introduction to processes in a fast-paced environment. Developing procedure-related documents for onboarding new emergency response staff allowed for faster onboarding and efficient and effective program management during the response. This experiential knowledge has been adapted into an internal surge staffing document for reference in future emergency responses. Internal and external surge staffing expanded the unit's ability to respond during the crisis, so documenting and developing procedure-related documents will be helpful for staffing the RCPU in the future.

Developing processes during an emergency response slowed down operations; the creation of SOPs before emergency response mobilization is recommended. For the RCPU, at the start of the response, there were limited resources to guide program managers through the process. There was a need identified to establish SOPs that considered context and restraints of emergency situations. In response, the RCPU created an emergency response manual that lists procedures to undertake in the event of emergency response activation. As the RCPU expanded its internal capacity during the response, it became evident that implementing partners were experiencing similar limitations in capacity and that guidance documents were needed. In alignment with an organizational strategic goal to help strengthen the public health system, the RCPU modified internal manuals to create external handbooks that partners can reference for fundraising and programmatic activities during emergency response.[2,3]

Another primary issue identified was the inefficiencies created by manual entry of data generated by projects. This initial tracking process was effective but placed a burden on program managers, as it was centered around a non-automated monitoring sheet requiring manual entry of each value, and a lack of resources to guide data collection processes. To address this, the RCPU Impact and Evaluation team created, piloted, and implemented a streamlined data collection process and accompanying templates for emergency response projects, including data trackers, logic models, evaluation frameworks, and automatic data reporting forms. Data systems trainings were also implemented to assist with streamlining and automating RCPU systems further.

Lack of clarity in emergency response roles and responsibilities across all CDC Foundation departments led to confusion in responsibilities and delays in processes needed to support rapid emergency response implementation. The RCPU Emergency Response Manual includes detailed descriptions of response-related roles and responsibilities of each internal department and unit and a primary point of contact for each department. In addition, the RCPU had limited structure for telling the stories of program activities and impacts, which limits what can be presented to funders and philanthropic entities that support emergency response work. To have more opportunities for sharing impact, the RCPU created a manuscript team and identified a process for storytelling of emergency response projects.

Limited evaluation of lessons learned during emergency response may lead to repetitive issues or gaps that become persistent over time. The RCPU now has plans to conduct an intra-action review during future emergency responses to ensure that the emergency response team is continuously learning from limitations and threats in emergency response work. The RCPU

Table 1
CDC Foundation Response, Crisis and Preparedness Unit intra-action review evaluation qualitative themes, subthemes, identified gaps, and actionable items taken to address gaps.

Intra-action review qualitative themes	Intra-action review qualitative subthemes	Identified gaps via intra-action review	Actionable items taken to address gaps identified: to address the identified gaps, the CDC Foundation's RCPU…
Staffing	• Employee roles and responsibilities • Onboarding and offboarding • Work-life balance • Communication with human resources • Shifting to emergency response priorities	Limited proper onboarding training resources in a central place led to delays in onboarding. Slow onboarding processes lead to delays in programmatic implementation. Confusion in onboarding roles and responsibilities leads to delays and duplication of efforts.	1. Documented specific departmental responsibilities for onboarding staff and identification of points of contact for each department 2. Created an internal surge staff plan for internal surge during emergency response 3. Created video training for onboarding processes, primarily regarding the use of platforms and necessary documents to review
Processes	• Proposal review processes • Meeting cadence • Internal organizational tools and platforms • Project metric and impact tracking • Project management and digital organization • In-unit engagement and management • Cross-departmental engagement and management	Contract negotiations with partners can be challenging and take time, and there are limited resources to guide program managers through this process. Manual entry for the project tracker leads to inefficiency and puts burden on program managers.	1. Created internal CDC Foundation Emergency Response Manual 2. Created emergency response manuals for fundraising and programmatic activities that can be referenced by partners to improve their emergency response operations 3. Developed and piloted an automatic survey form for subcontractor progress and final reports on Smartsheet 4. A shorter, letter-format agreement was created for community partners and faster review and execution of agreements to address challenging contract negotiations
Data systems	• Project metric and impact tracking • Daily use of platforms • Data collection and digital platform training needs	Lack of automatic systems to manage projects puts burden on program managers. Requirement of manual entry to data collection trackers puts burden on program managers.	1. Implemented trainings on data systems and platforms used for program management 2. Developed streamlined data collection process and templates for emergency response projects, including data trackers, logic models, evaluation frameworks, reporting forms for partners, donor reporting forms, etc.
Communications	• Email updates • Use of digital platforms and related preferences • External communication with programmatic partners • Program impact stories	Lack of clarity in emergency response roles and responsibilities across all departments leads to confusion in responsibilities and therefore delays in a process that needs to support rapid emergency response implementation.	1. Defined response-related roles and responsibilities of each department and unit within the emergency response manual 2. Designated primary points of contact in each unit for emergency response activities 3. Created a manuscript team and identification of process for storytelling of projects in emergency response
Next steps	• Impact measurements and frameworks • Risks and opportunities found in external partnerships • Staff capacity and emergency response responsibilities	Lack of structure for evaluating and telling the stories of program activities limits what can be presented to funders and philanthropic entities that support emergency response work. Limited evaluation of lessons learned during emergency response may lead to repetitive issues or gaps that become persistent over time.	1. Created program initiation and close-out checklists within personalized program management toolkits to guide program managers 2. Presently conducting an after-action review to understand lessons learned during the COVID-19 response

additionally has plans to conduct after-action reviews to follow up on lessons learned during intra-action reviews and to enforce actions that need to be taken to address gaps in the rapid implementation of projects.

Discussion

The intra-action review provided an opportunity for the CDC Foundation's RCPU to understand gaps in emergency response activities and how the CDC Foundation can better enable and augment the efforts of CDC and other partners. Expanding the process of conducting intra-action reviews and impact surveys to be a routine part of emergency response programmatic work before, during, and after public health emergencies allows for an efficient, impactful, and sustainable response. Creating feedback mechanisms to engage employees allows for the capture of successes and lessons learned to incorporate into current and future emergency response work. In addition, an analytical review of procedures enables the development and improvement of emergency response–related documents and the opportunity to create tools for public health partners that secure positive outcomes during future public health emergencies.

Limitations

The results of the intra-action review and operational improvements are primarily reflected on an internal level. The effectiveness of the external products created for partners should be further evaluated to understand their impact. Similar operations-related evaluations, such as an after-action review[1] should be conducted in the future to further understand how improvements affected the success of the response.

Author statements

Ethical approval

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Competing interests

The authors have no conflicts of interest, and all authors certify that this material has not been published previously and is not under consideration by another journal. The authors further certify that they have had substantive involvement in the preparation of this article and are fully familiar with its content.

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Themed Paper — Review Article

A scoping review of non-professional medication practices and medication safety outcomes during public health emergencies

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ABSTRACT

Objectives: Public health emergencies (PHE) can disrupt personal medication practices and increase the risk of medication-related harm and other negative medication-related outcomes. Our aim was to examine the extent and nature of published research on this topic to guide future research and practice.
Study design: Scoping review.
Methods: Standard electronic databases were searched. PRISMA-ScR guidelines were followed. Extracted data were organised in response to review questions and narrative accounts developed.
Results: A total of 129 studies were included, conducted across 32 countries, mostly in the USA ($n = 42$). Sixty-eight (53%) reported on infectious events, 49 (39%) climatological or ecological events and the remainder a mixture of terrorism, war or other disasters. The studies described several medication safety outcomes (medication-related harm, adherence, supply) and adaptive medication practices (self-altering prescribed medications, sharing medications and changing healthcare providers). Challenges to maintaining routine medication practices during a PHE included transport, finance, quarantine and knowledge-related issues. Twenty-eight studies (22%) examined health inequalities pertaining to adverse medication-related outcomes, with findings suggesting that gender, age, ethnicity, educational and socio-economic status may be related to inequalities. Research gaps identified included carers', children's and minority communities' experiences and intervention studies.
Conclusions: There is considerable evidence of disruptions to routine personal medication practices during PHEs and of medication-related harm and other negative outcomes. Maintaining medication supply for the management of chronic conditions is a universal problem across all emergency types. Research is needed to address these disruptions, particularly amongst people who experience health inequalities who may need additional support.

Introduction

Medications are the most common healthcare therapy and can cause unwanted medication-related problems.[1] These can significantly affect patients' lives. Medication-related problems have been shown to cause significant morbidity, with most harm being avoidable.[1–3]

Public health emergencies (PHEs) are defined as extraordinary events with associated health consequences that have the potential to overwhelm routine community capabilities to address them.[4] Recently, there have been several significant PHEs associated with infectious diseases, such as the COVID-19 pandemic, and

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climatological or ecological issues, such as flooding, hurricanes and earthquakes.[5] Potential issues associated with PHEs include reduced access to health care; supply chain interruption; changes in household mobility, personal well-being and routine support; and widening of health inequalities. These create additional challenges for medications safety, at times when preventing and mitigating medication-related harm and any associated healthcare utilisation are particularly important. Although previous studies have reported on the impact of PHEs and their implications for health care generally, the specific impact on medication management is less well known, particularly regarding lay people's medication practices and medication safety. Inappropriate changes in medication-related behaviour during a PHE may have adverse acute effects on individual health or necessitate the need for urgent healthcare intervention. They also have potential to worsen chronic ill health leading to poor individual and population health outcomes and greater strain on health services during all stages of a PHE. As such, there is an important need to optimise personal medication management/usage during and after PHEs.

Interest in medication-related harm and the lay burden of work associated with managing medication is rising.[1,6,7] We were keen to understand the impact of this in terms of personal medication safety. We are not aware of any systematic or scoping reviews of medication safety during PHEs. The aim of this scoping review is therefore to provide an overview of the extent and nature of the available research on laypeople's medication practices and medication safety outcomes at times of PHE. This review will assist in identifying medication safety issues during PHEs and responsive practices described in the literature, identify research gaps, and help guide future research and practice in this area.

Methods

Design

This scoping review was conducted in line with methodological guidance[8] and reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR; Supplementary Document 1).[9]

Review objective and questions

The aim was to provide an overview of the extent and nature of the available research on lay (non-professional) medication practices and medication safety outcomes at times of PHE. It was led by the following review questions (RQ), which were validated by discussion with informal carer and patient advocates:

RQ1. What study designs and characteristics have been used to examine medication safety vulnerabilities and non-professional medication practices before, during or after PHEs?
RQ2. What public and patient involvement occurred in the conduct of the research?
RQ3. What study populations and events were examined?
RQ4. What outcomes related to medication safety and non-professional medication practices/behaviours were described?
RQ5. What were the main findings of these studies?
RQ6. What interventions have been evaluated to address these behaviours and outcomes during PHEs?
RQ7. What outcomes were measured to evaluate these interventions?

Search strategy

Based on our research questions, a preliminary Ovid Medline search was designed to combine the concepts of medication practices or behaviours, medication safety outcomes and PHE. Subsequent searches were adapted and applied to CINAHL, PsychIfo, Embase, Global Health Cochrane Library, Prospero, Joanna Briggs Institute and Trip database. The search reviewed records from database inception to April 2021, with no limits to language or date range applied. Upon retrieval, results from all databases were deduplicated and exported for management into Covidence.[10] The study protocol and search strategy are provided in Supplementary Document 2.

Study selection

Title/abstract screening, followed by full-text review, was performed independently by two reviewers; conflicts were resolved by discussion or with a third reviewer. Articles were then iteratively reviewed for their relevance until group consensus on inclusion was reached.

Eligibility criteria

The inclusion and exclusion criteria are described in detail in Supplementary Document 2. In brief, we focused on studies conducted before, during or after a PHE; an unrestricted.[4] Our study population included all individuals, regardless of demographic or clinical characteristics; any qualitative or quantitative outcome reporting on non-professional medication use, practices or behaviours or medication safety outcomes that met the criteria. We used the term medication-related harm to refer to changes in patient's health status associated with medication use such as adverse drug reactions (ADRs) and changes to clinical outcomes. We have classified changes to supply and adherence issues separately. We included published peer-reviewed journal articles with empirical data. We screened the bibliographies of identified systematic or literature reviews and included the original studies that matched our inclusion criteria, while excluding the review articles themselves.

Data extraction and charting

Data charting against each RQ, using a Microsoft Excel template, was undertaken mainly by one reviewer with 10% of data from studies extracted by a second reviewer. Accuracy and consistency between all extractions were assessed by a third reviewer to determine the validity of continued extraction by one team member. Non-English studies were translated by team members or a volunteer who were confident to translate the paper into English.

Summarising and reporting the data

Data relating to RQs were synthesised from the charted data and reported as narrative accounts. Identified medication-related practices and outcomes were grouped into common themes. A PRISMA flow chart was prepared. We did not assess the methodological quality of the identified studies because of anticipated heterogeneity in study types and designs and in keeping with the standard practice for scoping reviews.[11]

Results

A total of 129 studies were included in the review (Fig. 1 and Supplementary Document 3), the majority reporting on infectious events ($n = 68$, 53%), climatological or ecological events ($n = 50$, 39%) and the remainder a variety of other disasters.

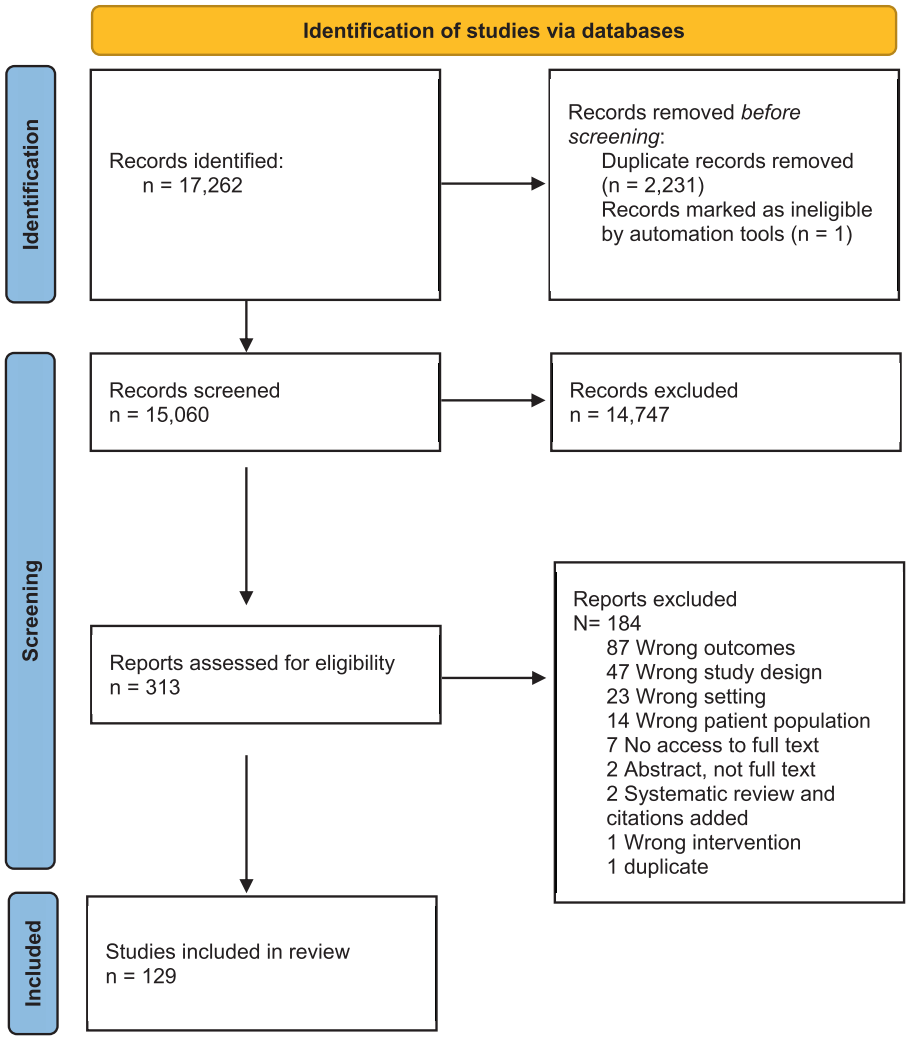

Fig. 1. PRISMA flow diagram.[138]

RQ1 and 2. Study characteristics and patient and public involvement

The earliest study identified was published in 1999, with the number of studies increasing substantially since 2020 (Fig. 2). Most were reported in English (n = 126). One study was published in each of Mandarin, German and Japanese. Most (n = 105, 81%) collected only quantitative data. Five collected both quantitative and qualitative data, and 19 (15%) collected only qualitative data. All included studies were observational by design. Most were undertaken within the mitigation and preparedness phases during the PHE (n = 62, 48%) or within the response and recovery phases afterward (n = 60, 47%). A further seven studies that focussed on disaster preparedness were not temporally aligned to a single specific PHE, but rather to the participant's previous experience of one of several possible emergencies. Sixty-nine studies (53%) reported no specific funding source and the remainder reported funding from multiple sources. Seven studies (5%) reported patient and public involvement in conduct of the research.[12–18]

RQ3. Public health emergency and participant characteristics

Study participants

Studies typically investigated an exclusively adult population (Fig. 2). Participants were recruited from a variety of settings, mostly the general population affected by the PHE (Fig. 2). Regarding healthcare condition, there was no restriction for the largest group of studies (n = 50, 39%); the remainder focussed on various disorders or body systems (Fig. 2).

Several studies investigated populations that may be at greater risk of health inequalities[19] including those with physical disability,[20–22] HIV,[23–33] mental illness[15,34–36] socio-economic deprivation,[14,37–39] refuge or displacement,[13,25,37,40–42] opioid or other substance misuse or dependence,[30,43–46] people of black and minority ethnicity[38,43,47] and men who have sex with men.[31,48]

Country and type of public health emergency

More than half (n = 68, 53%) of the studies covered infectious events, 57 (44%) of which were the COVID-19 pandemic (Fig. 3). Most were conducted in the Americas, the European region and the Western Pacific (Fig. 4) and in a single country (n = 123). Based on The World Bank's world economies classification, most studies (n = 83, 64%) were undertaken in high-income countries.

RQ4. Study outcomes measured

The identified medication safety outcomes were categorised into three themes: (1) medication-related harm, (2) medication adherence and (3) medication supply.

Fig. 2. A visual representation of the included studies. A) Frequency of publication per year by public health emergency type (presenting 2021 data to April). B) Type of study participants. C) Age profile of study population. D) Healthcare condition or body system investigated

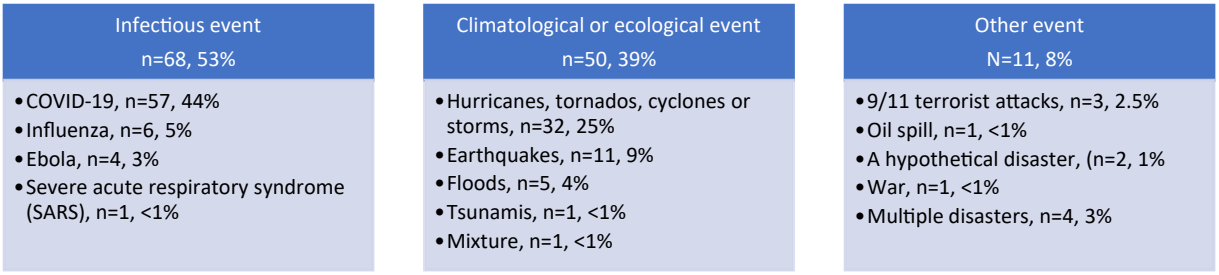

Fig. 3. Type of public health emergency studied.

Concerning medication-related harm, five studies reported ADRs.[46,49–51] Other patient health outcomes associated with medication use or omission included asthma control,[52] withdrawal from opioids,[43,44] uncontrolled hypertension,[53] autoimmune hepatitis relapse,[54] seizure frequency,[21] glycaemic control[55] and perceived and actual rheumatic disease activity[56] and long term health status following myocardial infarction.[57] Anxiety related to medication use was another common health outcome reported qualitatively and quantitatively via prompts in surveys and fears and concerns self-disclosed during interviews.[15,28,51,58–67]

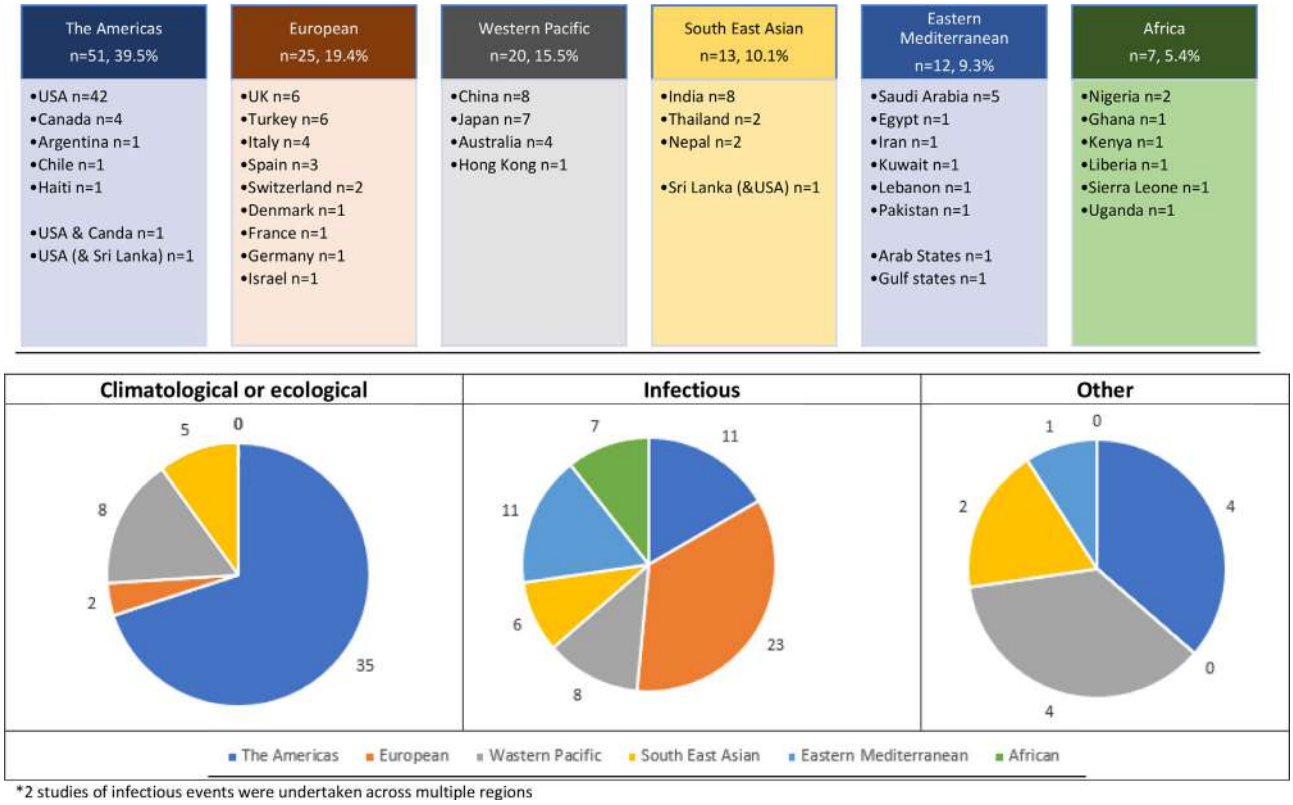

Fig. 4. Public health emergencies studied by geographic region and type.

A quantitative outcome of 'adherence' or 'compliance', as termed by the study authors, was reported in 30 studies, using four distinct measurement types: (1) A discrete self-report at one time point using a variety of phrasing of questions (n = 24),[24,25,32,33,36,53,56,61,68–79] (2) a discrete single time point measure comparing two study groups,[54,57,80] (3) discrete measures at two times points[16,23,81–83] and (4) calculated based on days of tablets remaining.[28]

Effects on lay medication practices, reported qualitatively and quantitatively, were categorised into four themes: (1) accessing medication supply, (2) altering prescribed medication regimens, (3) accessing professional or lay support or services or (4) storing, administering and monitoring the effects of medication. Quantitative measures included using disaster risk assessment tools[14,84,85] (n = 3) and surveying experiences.[17,18,35,47,48,51,56,59,62,64,66,72,74,78,81,82,86–91]

Twenty-eight studies examined outcomes by population groups at greater risk of health inequalities:[19] gender,[12,26,29,38,43,50,52,86,92–95] age,[26,29,38,43,50,52,60,77,93,94,96] race/ethnicity[38,40,50,52,65,93,97,98] socio-economic,[26,29,43,50,52,96,98,99] educational,[26,43,52,60,77,95,96] marital[26,43,95] or other[15,23,25,29,34,43,60,93,95,98,100] status.

RQ5. Study findings

Medication-related harm

Published reports of ADR during a PHE most frequently related to antiviral medicines administered during the 2009/2010 A/H1N1 influenza pandemic in the UK and USA,[46,49,50] and cancer chemotherapy.[51] One study reported an increase in perceived ADRs associated with self-medication during the COVID-19 pandemic, and more frequently in those taking chronic illness medication than others.[95]

One study found epileptic seizures worsened for some patients immediately after an earthquake, attributed to lack of access to medication (5.6%).[21] Two studies after hurricane Sandy reported an increased risk of relapse,[43] and withdrawal,[44] and changes in injection behaviours among opioid and intravenous drug using populations who were accessing substitution services predisaster.[43,44] Following the World Trade Centre disaster, an inverse relationship between adherence to long-term preventer medication and asthma control was identified amongst rescue workers with mental health viewed as a modifying factor.[52] Poor glycaemic control during COVID-19 was associated with medication non-adherence in type-2 diabetes, but not type-1 diabetes, with accounts of hyperglycaemia and diabetic ketoacidosis.[55] Altered adherence was associated with: uncontrolled hypertension following a hurricane;[53] perceived rheumatic disease activity[56] and exacerbation of rheumatic symptoms[58] during COVID-19; and index presentation to hospital with an acute myocardial infarction.[57] During COVID-19, telehealth was associated with a beneficial effect on medication compliance and lower rates of relapse of autoimmune hepatitis.[54]

Several studies reported patient anxiety around medication use associated with an emergency. Patients experienced anxiety about general medication issues[101] and fear about maintaining access to medication supplies.[60,66,67] Anxiety reportedly contributed to both decreased[15,28,51,58–64] and increased[60,91] use of medication. A fear of accessing healthcare facilities was associated with changes in medication-related behaviours,[33,64,67,78,89,102] while fear of infection was reportedly associated with medication stockpiling[103] and decreased medication adherence.[28,62]

Medication adherence

Several studies reported non-adherence to prescribed medications after a PHE, but without comparison to pre-PHE adherence

levels[15,53,56,75,76,78,79,104] (Supplementary Document 5). Some studies reported little or no change to adherence during a PHE.[29,36,71,82,91,105,106] Notably, this did not always mean similar health outcomes. For example, one study found most people reported remaining adherent to their epilepsy medications, while simultaneously observing an increase of >50% of seizure frequency, attributed to stress and lifestyle changes.[71] Both improved and worsened adherence was reported.[36,71,72,74] For example, during one survey of 282 patients with cardiac disease during COVID-19, participants felt the pandemic had no effect on their medication compliance (73%), improved it (18%) and decreased it (10%).[74]

Medication supply

Twenty-seven studies quantified the prevalence of running out or having interruptions to medication supplies (Supplementary Table 5). The duration of medication shortages varied between studies, ranging from days to weeks.[29,42,55,69,87] Hydroxychloroquine was reported to be in short supply in three studies during COVID-19.[64,90,107] Being evacuated or displaced from home and forgetting to bring medicines[20,45,53,97,98,101,108] were reported as affecting adherence. Barriers to obtaining medications included transport/relocation[16,25,35,45,89,109–112] and financial[20,25,27,55,71,80,89,115] and regulatory[27] issues. Delays in prescription deliveries were reported.[47]

Practices related to altering prescribed medication regimens

Use of long-term immunosuppressant therapy for chronic disease management reduced during COVID-19 due to perceived increased risk of infection, with medications stopped either temporarily or completely and sometimes without medical advice.[18,54,56,58,59,61–64,88,107,113–116] Patients requested to change their immunotherapy early into the COVID-19 pandemic but that requests to switch were no longer made later in the pandemic.[18] Patients made changes to their prescription medication regimen, without medical advice, including increased dosage,[18,56,106] decreased dosage or frequency of administration,[18,56,90,106,107,115] rationing medication,[117] interrupting or suspending medication,[51,61,62,64] stopping medication use[54,59,62,63,107,113–115] and restarting previously used medication.[61,63]

Practices and barriers related to accessing medication supplies

People responded variably to the altered access to medication supplies. For example, attending a healthcare practitioner earlier than needed;[67] maintaining an extra supply of medication;[21,67,109] keeping medication separately in several places to support access;[21] bringing medications, medication lists and insurance cards with them when evacuated;[27,118] sharing medications (insulin and buprenorphine) between friends or acquaintances;[44,119] rationing medications.[46,117] In the aftermath of a hurricane, people with substance dependence were reported to move from prescription supply to illicit supply,[46] and increase risky behaviours such as sharing needles or drug preparation equipment due to lack access to methadone dispensing and closure of needle exchange centres.[43,44]

Lack of knowledge was reportedly associated with lack of preparation of medication supplies, and lack of recognition of the risk of adverse effects of running out of medications.[14,27,70,109] Inadequate knowledge of one's medical history or records of medication names and dosages was identified as problematic for arranging a new supply of medications.[27,120] Difficulty communicating with healthcare providers online or inability to contact them to order a prescription or access treatment was occasionally reported as a barrier to medication supply.[47,48,78,121]

Practices related to accessing support or services

People accessed alternatives to their regular healthcare providers during an emergency, for example, doctors and hospitals[21,79] and pharmacies[38,53,90] in a different location. The use of an online children's asthma action plan reportedly decreased medical expenses during COVID-19.[83] People accessed health care to support their coping with the PHE, for example, accessing counselling services was associated with a greater likelihood of medication use[93,122] and commencing medication use as a coping mechanism.[27,93,108,122] Having social support from other people ('social capital') was reportedly associated with increased adherence,[23,25,122] the sharing of information and medication supplies[25,37] and the purchase of medication for others.[79]

Practices related to storing, administering and monitoring the effects of medication

Two studies described medication storage issues including medication being accidentally thrown out[25] and difficulty refrigerating medications during an evacuation.[20] Lack of assistance to administer medications[22,45,109,112,123] was reported to affect adherence. Lack of privacy in a communal refugee space resulted in covert medication self-administration and decreased adherence.[25] Lack of access to food was problematic for medications that should be taken with food.[25] Self-efficacy was an identified barrier to medications taking.[24,25,76] Financial issues were associated with (non-)adherence to medication monitoring recommendations.[55]

Inequalities

Access to medicine supplies was associated with racial/ethnic,[50,97,98] age,[94] socio-economic,[50] educational,[26] health[25] and displacement[34] status: Black and minority ethnic groups, older, less educated, socially deprived and those who were displaced experienced greater challenges accessing medication. Existing social inequalities were reportedly widened through favouritism of selected communities for distribution of medication supplies.[25] Medication non-adherence and treatment failure was associated with religious status and stigma amongst people living with HIV who attended a treatment centre daily following an earthquake.[23] Women were identified as more likely to administer medication to infected patients during a pandemic, thereby exposing them to greater risk than men of contracting the infection through caring duties.[12] Drug misuse or illicit drug use in those experiencing dependence was associated with age,[29,60] social support,[29] educational,[60] occupational,[99] health[60] and socio-economic status.[99] Females had greater medication use needs than males following a PHE, for example, needing medication refills or commencing hypnotic use.[14,86,92,93,95] Inferior glycaemic control in people with diabetes who were home quarantining during COVID-19 was reportedly more common in younger people and those with a greater number of years' education.

RQ6 and 7. Interventions evaluated and outcomes measured

Five studies described interventions that were implemented during PHEs; these were an action research study,[13] a mixed-methods study[42] and three cross-sectional studies.[26,83,110] Provision of extra take-home medication doses was associated with sustained access.[13,26] Provision of information about anticipated clinic closures and access to alternative clinics were considered as modifiable factors that can potentially help sustain medication access.[26] Implementation of a multicomponent intervention for the management of hypertension and diabetes in a humanitarian situation identified the challenge of large-scale implementation in the field and the limited impact of the programme on continuity of medication supply.[42] A study observed the feasibility and acceptability of

administration of medications for headache, reported to be a common health issue during a natural disaster.[13] Provision of an online platform for children with asthma was associated with improved medication adherence and reduced medical expenses.[83] Finally, provision of an information kit about preparing for an emergency to a cohort of dialysis patients resulted in a self-perceived improvement in disaster preparedness in a subsequent follow-up survey.[110]

Discussion

This scoping review provides the first systematic overview of studies exploring lay, non-professional medication practices and medication safety outcomes during events of major public health concern. The review identified medication-related harm, adherence, supply, alteration of prescribed regimen and issues with the storage, administration and monitoring of medication as outcomes that have been assessed, both quantitatively and qualitatively. People's practices related to accessing medicines, support or services were commonly reported. The associations between health inequalities and medication-related outcomes and practices were frequently explored. The evidence suggests that medication-related problems are common during PHEs, that people adapt their medication use behaviours to respond to these challenges and that pre-existing inequalities may be widening during PHEs and affecting medication outcomes. The coming section summarises the evidence for each research question and the implications for future research.

RQ1 study design and characteristics

Included studies used mostly observational designs with limited potential to inform whether the medication management issues identified were associated with the emergency or whether they occurred routinely during 'normal' times. Few studies were published in non-English languages, possibly reflecting the databases searched, or the dominance of the English language in science and social science.[124] Other methodological challenges identified were the lack of pre- and postreporting of medication adherence rates, and limited follow-up to assess long-term clinical impact. We acknowledge that comparative or prospective studies are challenging due to the unplanned and unpredictable nature of PHEs. Future research should use comparative and experimental designs if possible and explore the long-term impact of PHEs.

RQ2 patient and public involvement

The absence of community engagement in this review is a clear research gap. Involving patients and the public in research has been widely recognised as a useful method to increase the relevance, use of research findings[125,126] and sustainability of new interventions in humanitarian settings.[127]

RQ3 study population and emergency characteristics

The relative absence of studies conducted in low-income countries supports the recent call to prioritise global medication safety research efforts in low- and middle-income countries.[125] Several studies focused on marginalised groups and many studies considered disadvantaged groups or specific clinical groups more vulnerable to certain medication-related harm during PHEs. The current literature extensively explores multiple clinical conditions and disease states but provides limited insight into the experiences and perspectives of children or informal caregivers. Given the increasing prevalence of vulnerabilities associated with informal caregivers' medication management, it is a potential area for future study.[128] Few studies included complementary and herbal medications,[12,107,129,130] and this may also be worthy of future exploration.[131] COVID-19 accounted for almost half of the studies included in this review, likely reflecting its scale and impact worldwide. The review also included numerous studies set in the aftermath of climate disasters, mainly in the USA, and information about the experiences in other jurisdictions is relatively lacking.

RQ4 outcomes measured

The key outcomes reported in this review were medication-related harm, adherence and supply, although few studies reported on the long-term health consequences of these. There was an absence of exploration about how education on new and routine medication, and altered medication monitoring, affected long-term health outcomes. The inconsistent use of definitions, terminology or validated measures jeopardised the potential quality of the included research. For example, several studies reported challenges with obtaining medication supply in the short term as non-adherence or non-compliance, despite the outcome reflecting a discrete event rather than a behaviour over time. Therefore, ostensible findings regarding 'adherence' potentially misidentify an organisational problem related to lack of continuity of medication supply with a personal pattern of medication use. This could affect development of effective solutions to improve patient outcomes during a future emergency.[132] Several studies measured doses missed during an emergency but failed to assess their clinical significance, a missed opportunity to differentiate more critical issues that should be addressed to mitigate harm.[133]

RQ5 findings

The review provided considerable evidence of disruptions to routine medication practices but less evidence about the impact of these disruptions on short- or long-term health outcomes. There is some evidence that these disruptions may contribute to stress, anxiety and other negative outcomes.

Self-alteration of medication was commonly described in studies. This is a new concept that typically involved medication discontinuation, reduction of immunosuppressant use or increased medication taking. During COVID-19, there was unprecedented sharing of information online.[134] We hypothesise that self-alteration of prescribed medications could arise in response to: (1) health anxiety, (2) changing routines, (3) interrupted medication supply, and (4) uncertainties about the (side) effects or efficacy of medication when a new infectious disease is not well understood. The appropriateness of self-alteration and its impact on clinical or humanistic outcomes may support understanding of whether health behaviour modification techniques are merited.

The review identified that disadvantaged population groups are more vulnerable to negative medication-related outcomes during PHEs, and that PHEs may indeed exacerbate and widen pre-existing health inequalities, both directly and indirectly. Research is needed to determine the actions required to mitigate this.

RQ6-7 interventions to address identified problems during PHEs

The review identified few interventions to address medication safety outcomes during PHEs. There is an opportunity to address this by prioritising the identified medication-related challenges: medication adherence, supply and self-alteration. Our findings suggest that the public may not perceive medication-related hazards as a threat during PHEs despite evidence of them resulting in negative patient outcomes. Improving preparedness may mitigate medication-related harm. Emphasising the importance of household-based preparedness such as keeping a written/printed

record of medications in a safe and accessible place(s), and providing basic resources to affected communities may also be protective.[128] Further exploration of system-level changes to medication supply that have proven helpful in emergencies may support lay medication practices in future emergencies. This echoes calls for targeting systemic and organisational issues which contribute to medication risk.[125]

Strengths and limitations of this review

The main strengths of this scoping review are that it provides a comprehensive overview of the available published literature on this topic, with no restriction on language and inclusive of a wide range of databases. The review followed a rigorous methodological framework for scoping reviews, which assures consistency and structure of the search process and confidence in the reporting of findings. We did not assess the quality of the studies, as is typical for a scoping review. Regarding patient and public involvement, whilst we did validate the research questions with informal carer advocates, there were opportunities for deeper engagement, potentially following published guidance on stakeholder involvement in systematic reviews.[135] Heterogeneity was introduced into the review by including different types of PHEs; future research should synthesise the issues and outcomes specific to certain PHE types. The review includes only studies published before April 2021 and therefore more recent evidence may be missing. However, the high volume of studies provided adequate data to respond to the research questions. The findings and discussion points regarding gaps in research should help to define an agenda for future research.

Conclusions

There is a considerable level of research evidence suggesting that medication supply and patient adherence are impaired during PHEs, that medication-related harm occurs commonly, and people adapt their medication regimen, without healthcare advice, in response to challenges experienced. The review identified that PHEs can widen pre-existing inequalities resulting in a disproportionate effect on medication outcomes for marginalised and minority groups. Despite this, we found very few interventions targeting lay, non-professional medication practices.

Author statements

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Competing interests

The authors have nothing to declare.

Appendix A. Supplementary data

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Review Paper

Can legionellosis be considered an occupational risk in the healthcare sector? A systematic review and meta-analysis

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ABSTRACT

Objectives: According to current knowledge about legionella transmission, healthcare workers (HCWs) are at an increased risk of exposure. The aim of this research was to systematically review the literature about HCWs' exposure to legionella and establish whether there is an occupational risk.
Study design: This was a systematic review and meta-analysis.
Methods: PubMed, Scopus and Web of Science were searched to identify studies regarding the occupational risk of legionellosis for HCWs. Keywords used in the search were *'Legionella pneumophila*', 'occupational medicine', 'occupational' and 'risk'. Selected studies were reviewed to assess the quality and meta-analysed. Finally, the nine epidemiological principles of Bradford–Hill criteria were used to assess whether legionellosis could be considered an occupational risk for HCWs.
Results: The search strategy retrieved 124 studies, and 10 studies were included in the present review. The overall study quality was low. The pooled odds ratio estimate was 2.45 (95% confidence interval: 1.52–3.96). The assessment using Bradford–Hill criteria showed that only two criteria (plausibility and coherence) were met, which is insufficient to establish an occupational risk.
Conclusions: This systematic review suggests that there is a higher risk of legionella exposure for HCWs, but there is currently no clinical evidence. Further studies with appropriate study design are needed to determine whether legionella infection is an occupational risk for HCWs.

Introduction

Legionella is a bacterium that is widespread and can be found in environmental water sources. From the natural source, it passes into sites that constitute an artificial reservoir (e.g. channelled water in towns, water systems in individual buildings, etc.). Water temperatures in the range of 20°C–45°C favour the growth of the organism. The presence of sediment, sludge, scale, rust and other materials within the system, together with biofilms, also provide favourable conditions in which legionella may grow.[1]

Each year, the European Centre for Disease Prevention and Control reports the epidemiological trend of legionellosis. In 2020, 27 countries reported 8372 cases; the number of notifications decreased to 1.9 per 100,000 population, which was lower than the two preceding years (e.g. 2.2 per 100,000 population in 2019) and is in contrast with the trend observed in previous years. The COVID-19 pandemic may have influenced this observed decrease in reported cases because of travel restrictions and societal changes, which may have led to differences in population exposure to Legionella risk sources. In addition, increased pressures on healthcare systems and changes to testing protocols may have resulted in underreporting. Four countries (France, Germany, Italy and Spain) continued to account for the majority of notified cases (72%), whereas several countries continue to have very low notification rates (<0.5 cases per 100,000 population), which is likely to represent an underestimation of the incidence in these countries. It is important to note that in 2020, proportionally more outbreaks were reported to be associated with hospitals compared with previous years, although the numbers were similar to previous years.[2]

In 2019, 3199 cases of legionellosis were reported in Italy. The number of notifications increased to 3.19 per 100,000 population, which was higher than the preceding years (2.96 per 100,000

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population in 2018 and 2.037 per 100,000 population in 2017), showing an increasing trend over the years. In Italy, a North-South gradient is observed, with a higher incidence of legionellosis in northern regions. In addition, data about nosocomial infection were reported 121 cases; of these, 60 cases were linked to 22 nosocomial clusters.[3] In 2020, the number of notifications in Italy decreased to 2074 cases, probably influenced by the COVID-19 pandemic, as reported in European data.[4]

Healthcare workers (HCWs) should be considered at an increased risk of exposure to Legionella because these bacteria are widespread in healthcare facilities,[5–7] and several outbreaks have been previously reported.[8–10]

Legionella bacteria have been isolated in the majority of hospital water distribution systems in Italy, possibly as a result of a large number of old buildings in this country. Patients are known to be at risk of acquiring legionellosis in hospitals with contaminated water, but little is known about the risks to hospital staff.[11]

To diagnose legionellosis, polymerase chain reaction and/or sputum culture, serological evaluation and urinary antigen tests (UATs) are widely used. Currently, diagnosis of LD relies almost solely on the UAT, which has moderate and high sensitivity and specificity, respectively; thus, UAT is a useful method for the early detection of Legionellosis caused by *Legionella pneumophila* serogroup 1 (Lp-1) but less useful from an epidemiological point of view because it does not recognise LD caused by non-Lp1 strains.[12] Serological methods are useful for retrospective epidemiological investigations as they also allow assessment of previous infections, which may have been asymptomatic, thanks to the long duration of the antibodies, which eventually decline within 3–18 months.

In addition, the actual disease burden is likely to be underestimated, given that LD cases presenting as non-descript community-acquired pneumonia may be treated empirically using broad-spectrum antibiotics, leaving the disease and potential outbreak-related disease clusters unrecognised and unreported.[13]

Legislative Decree 81/2008 is an important regulatory reference for the management of legionellosis risk, providing a series of measures and indications to be followed by employers to prevent the risk of contagion from legionella in the workplace. Title X and Annex XLVI classify Legionella as a group 2 biological agent.

Guidelines and standards have been developed by various agencies and professional groups (e.g. Centers for Disease Control and Prevention [CDC], Occupational Safety and Health Administration, Environmental Protection Agency and American Industrial Hygiene Association). The National Institute for Occupational Safety and Health has provided recommendations to employees, healthcare providers, employers and building managers to reduce the risk of legionella growth and exposure.[14]

In Italy, the 'Guidelines for the prevention and control of legionellosis' (7 May 2015) aimed to unify and integrate all the indications given in a single text from previous national guidelines.

The CDC has also made available 'The Toolkit for Controlling Legionella in Common Sources of Exposure', which provides public health and building owners and operators with concise, actionable information on controlling legionella in commonly implicated sources of LD outbreaks.[15]

As a result of the various regulatory measures related to the epidemiological emergency from COVID-19, there has been a suspension or drastic reduction in the management of many buildings, leading to prolonged stagnation of water in internal distribution networks. The National Institute of Health has developed a guide for managers of facilities that are at increased risk of legionella transmission as a result of building closures and/or decreased use, including tourist accommodation and other buildings with civil and industrial use, on how to control its proliferation. For facilities that have been closed for a period of <1 month, a normal control regimen is applied; however, for longer periods, the need to apply additional control measures is indicated, regarding temperature, presence of adequate levels of disinfectants and proper water circulation, in addition to the detection of negative samples before the facility reopens.

The present study aims to systematically review the literature regarding HCW exposure to legionella, evaluating the prevalence in this population, and establish whether there is an occupational risk.

Methods

A systematic search was carried out to assess the occupational risk for HCWs by evaluating the incidence and mortality of legionellosis in this population. Methods for this study were developed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[16]

Search strategy

Identification of relevant studies was achieved by electronic database searches, including PubMed, Scopus and Web of Science, of the published literature. The following keywords were used:

- (*Legionella pneumophila* AND occupational AND Risk)
- (*Legionella pneumophila* AND occupational medicine)

The search was undertaken with no language or publication restrictions.

Study selection

The review process consisted of a multistep approach, including title and abstract screening, followed by full-text assessment. Any articles that were deemed relevant by the authors were included in the full-text assessment. Duplicate articles were filtered using the JabRef 5.2 (GitHub -Sindelfingen, Germany) software. After title and abstract screening, full-text articles were assessed to determine if they met the inclusion criteria. In cases where a selected publication was not available as full-text in the English language, the corresponding author was contacted to check if the eligibility criteria were fulfilled. If no reply was received within 4 weeks, the article was excluded from the analysis.

Inclusion criteria

The inclusion criteria are shown in Table 1.

Data extraction and quality assessment

Data extraction was conducted in duplicate by two authors, independently, extracting data from all included studies. A data collection sheet was developed to confirm study relevance and to extract study characteristics. Study characteristics included publication year, study design, country, incidence and mortality. To ensure accurate data collection, the extracted data from the two independent authors were compared. Any discrepancies and disagreements were discussed and resolved through a consensus session with a third author.

A quality assessment was performed using the Newcastle–Ottawa scale for observational studies.

Statistical analyses

All meta-analyses were performed using Episheet. The outcome variables were continuous random variables and were assessed using odds ratio (OR). The heterogeneity of effect sizes across studies was

Table 1
Inclusion criteria of the systematic review.

Population	Healthcare professional
Phenomena of interest	Prevalence and Incidence of legionellosis (odds ratio), mortality
Comparators	Any
Outcomes	All
Timing	All
Study types and designs	Cross-sectional study, cohort study

assessed using the Chi-squared test. Subgroup analyses were performed by setting and year of publication. Sensitivity analysis was conducted by excluding each study and rerunning the meta-analysis.

Results

The literature search was performed on 11 November 2021. The search provided 124 articles after duplicates were removed; eight of these articles, plus an additional six articles identified through other sources, were assessed for eligibility. Finally, 10 articles were included in the qualitative and quantitative analyses[11,17–26] (Fig. 1).

Five articles were published between 1987 and 1992,[17–21] four articles were published between 2003 and 2008,[11,22–24] and one article was published in 2017.[25]

A study conducted in the United States,[26] which initially seemed to satisfy the inclusion criteria, comprising 5431 dental HCWs, was excluded because it included inactive dental HCWs as the control group. This was not considered an appropriate selection due to the nature of the study; using antibody titer as a benchmark of a previous infection, inactive dental HCWs have the same risk of having antibodies compared dental HCWs who are still active, as shown by the OR estimated in this study (OR: 1.0007, 95% confidence interval [CI]: 0.69 − 1.44).

The population of interest in this study are HCWs. Specifically, this review included medical doctors, nurses, dentists, assistants and technicians. Control populations consisted of administrative personnel, blood donors and the general population. All included studies were cross-sectional studies. The characteristics of each study are shown in Table 2.

Evaluation of the included studies showed low quality levels. ORs were calculated to assess possible occupational exposure by comparing the proportion of seropositive people between HCWs and control groups. Overall, the results showed an increased prevalence of legionella antibodies among HCWs.

The meta-analysis (see Fig. 2) showed an increase in the prevalence of seropositivity among HCWs. The OR was 2.45 (95% confidence interval [CI]: 1.52–3.96), with twofold increased likelihood of HCWs having legionella antibodies.

The heterogeneity test highlighted differences between the included studies.

A subgroup analysis (n = 7), excluding studies that only included dental HCWs, showed no significant differences (OR 2.66 [95% CI: 1.47–4.82]), with heterogeneity between studies. When analysing studies that only included dental HCWs (n = 3), the OR calculated was 2.03 (95% CI: 0.77–5.31), and the result was not statistically significant.

A further subgroup analysis was conducted on studies published before 2000, resulting in an OR of 3.13 (95% CI: 1.56–6.26). Whereas, when analysing studies published after 2000, the OR was 1.89 (95% CI: 0.91–3.94), showing a lower and not statistically significant result compared with the OR for studies published before 2000.

Sensitivity analysis revealed that no single study changed the overall results.

Bradford–Hill criteria

Bradford–Hill criteria were used to determine whether legionellosis can be considered an occupational risk. The Bradford–Hill criteria are a group of nine principles that can be useful in establishing epidemiological evidence of a causal relationship between a presumed cause and an observed effect. The Bradford–Hill criteria have been widely used in public health research. The following criteria were analysed.

Strength

This criterion was not fulfilled because all the included studies were cross-sectional analytical studies that analysed the prevalence of antibodies directed against various legionella strains, and although the meta-analysis showed a higher risk of seropositivity, it was possible to prove contact with the bacterium, but not subsequent disease.

Consistency

Considering the repeatability of observations in different times, circumstances and places, the following criterion is not considered fulfilled because the studies cover an important period (1986–2017), but seven studies were carried out in Europe (Italy, the United Kingdom, Germany, Austria, Denmark) and three in America (the United States and Canada), thus representing only two continents. In addition, observational studies are subject to different forms of bias and evaluation of the quality of the studies through a Newcastle scale Ottawa modified for cross-sectional studies, revealed low scores for most studies.

Specificity

Legionellosis, despite being an infectious disease, does not show specificity. This is due to the particular mode of transmission of the bacterium through contaminated aerosols because an interhuman transmission was not proved, but only hypothesised.[30,31] In addition, exposure to the bacterium, demonstrated both by the isolation of it in the waters of the structures and by the presence of antibodies in HCWs, does not always lead to the development of the disease. However, it should be noted that questionnaires were administered in the studies to assess any other exposures to risk factors, in addition to the workplace, and an assessment of prevalence variations based on these factors reported no statistically significant changes.

Temporality

Since this study is considered an infectious disease, it is exposure to the bacterium that eventually leads to the development of the disease. All included studies are cross-sectional, and seropositivity was used as the outcome; thus, it is not possible to unequivocally fulfil this criterion.

Biological gradient

No significant differences were found in hospital/dental personnel seroprevalences based on the amount of exposure daily, but an increase in prevalence was seen in HCWs based on years of service.[11]

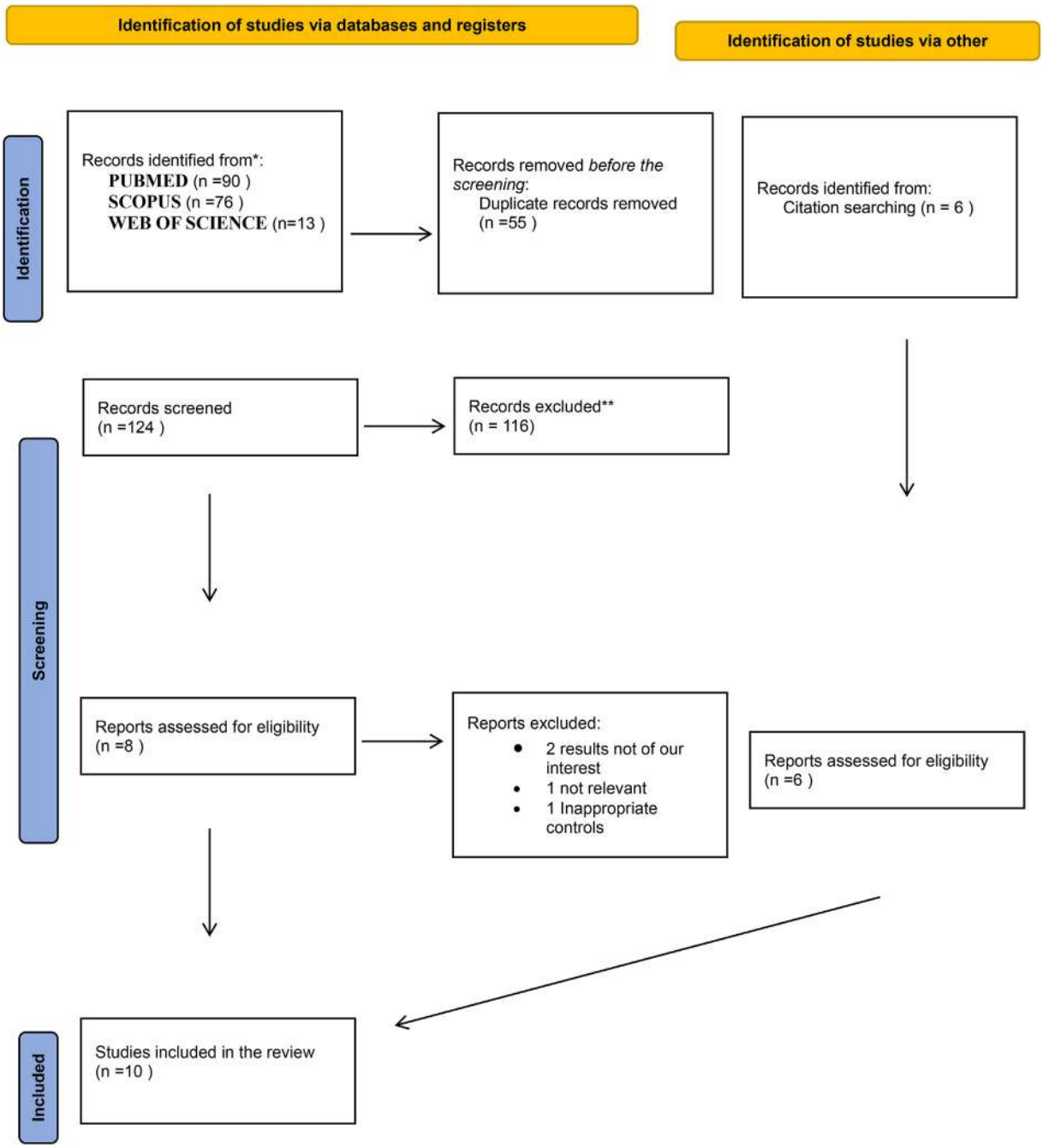

Fig. 1. PRISMA flow diagram showing the selection of articles about the occupational risk of legionellosis in healthcare workers (literature search performed on 11 November 2021).

Plausibility

According to existing knowledge, the following criterion was fulfilled because HCWs are exposed to contaminated sources (aerosols), as demonstrated by the isolation of bacteria in the water systems. However, it is difficult to assess the actual exposure in the studies because the levels of contamination are not stable but are conditioned by climatic variations, construction activities, maintenance, other environmental factors and the presence of antibodies.

Coherence

Data are related to seroprevalences, thus only provide information about contact with the micro-organism, not the disease itself (with the exception of questionnaires that investigated the presence of symptoms related to legionellosis). These data can be considered consistent with the knowledge about the natural history and biology of the disease because an increased risk of exposure has been shown in HCWs compared with the control population. However, it was not possible to review an adequate number of cases in HCWs, consistent with the rarity of this disease, which, even in the course of epidemic outbreaks, shows low rates of infection (>5%). This criterion was fulfilled.

Experiment

Because legionellosis is a rare disease and there is insufficient observational evidence, it was not possible to refer to previous results (experimental or semiexperimental). Preventive control measures could be put in place, such as adequate surveillance and

Table 2
Characteristics of the selected studies.

Study	Country	Year	Occupationally exposed	Unexposed	Seropositive HCW	Seropositive controls	OR (95% CI)	Quality	Sources	"High risk" population
Fotos PG et al.[17]	The United States	1985	Dentists, assistants, clinical-level students	General population	20.0% (54/270)	10.4% (7/67)	3.10 (1.19–8.09)	3	Not specified	Not specified
Marrie TJ et al.[18]	Canada	1986	HCW	Blood donors	4.8% (23/477)	1.9% (18/958)	2.56 (1.34–4.80)	3	Water distribution system	Included
Reinthaler F, Mascher F[19]	Austria	1986	Dentists, assistants, technicians	White-collar workers, non-dental students	33.6% (36/107)	4.7% (5/106)	10.24 (3.83–27.38)	2	Water distribution system	Not specified
Oppenheim BA et al.[20]	The United Kingdom	1987	Dentists, clinical-level students	Last-year medical students, young doctors	5.9% (9/152)	1.4% (1/70)	4.34 (0.75–34.97)	3	Water distribution system	Not specified
Luck PC et al.[21]	Germany	1992	Dentists, assistants	General population	6.9% (15/218)	5.5% (16/293)	1.27 (0.62–2.65)	2	Water distribution system	Not specified
Pankhurst C L et al.[22]	The United Kingdom	2003	Dentists	Blood donors	0.4% (1/246)	2.4% (12/500)	0.16 (0.02–1.28)	6	Water distribution system	Included
Vogt KL et al.[23]	The United States	2005	Dentists	Clinically unexposed volunteers	8.6% (93/1076)	9.1% (2/22)	0.94 (0.22–4.11)	5	Water distribution system	Included
Borella P et al.[11]	Italy	2008	Dentists, doctors, nurses, technicians	Blood donors, administrative personnel	45.3% (106/234)	34.4% (83/241)	1.31 (0.93–1.85)	3	Water distribution system	Included
Rudbeck M et al.[24]	Denmark	2009	HCW	Blood donors	81.7% (116/142)	29.7% (162/546)	2.75 (2.03–3.72)	4	Water distribution system	Included
Kevorkyan A et al.[25]	Bulgary	2017	Doctors, dentists	General population	69.2% (27/39)	8.4% (7/83)	8.20 (3.29–20.48)	2	Water distribution system	Included

CI, confidence interval; HCW, healthcare worker; OR, odds ratio.

purification of water or the use of personal safety devices (dpi), but it would be difficult to observe how the frequency of events could be affected by this intervention.

Analogy

Despite being an infectious pathogen, the particular modalities of transmission of the legionella bacterium make it difficult compared with other microorganisms.

Therefore, two of nine of the Bradford–Hill criteria were met when considering the studies included in this review.

Discussion

This review found that HCWs have a twofold increased likelihood of having antibodies against legionella, showing that this population of workers has a higher chance of encountering the

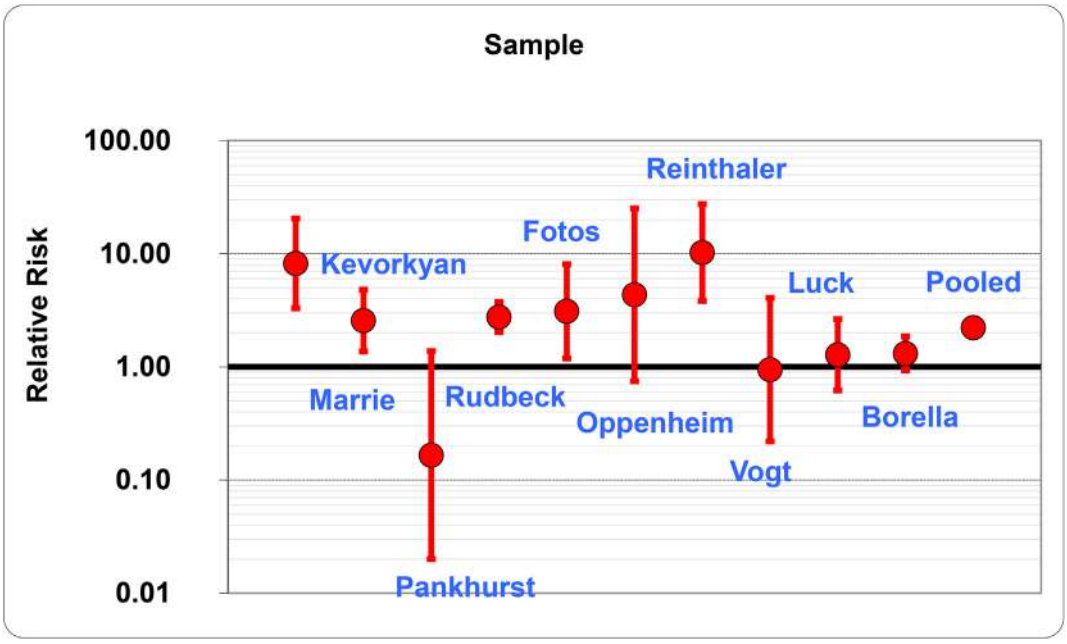

Fig. 2. Results of the meta-analysis.

bacterium. This result is in line with current epidemiological knowledge. Healthcare environments have been shown to be one of the most at-risk environments for the spread of legionella and other water-borne pathogens, as reported by Scanlon et al., particularly as a consequence of construction activities. However, a water management programme should have been established in such situations, in accordance with the American National Standards Institute and American Society of Heating, Refrigerating and Air–Conditioning Engineers Standard 188 Legionellosis: Risk Management for Building Water Systems and the CDC Toolkit Developing a Water Management Program to Reduce Legionella Growth & Spread in Buildings.[34] Contagion witkhin these facilities is probably due to the hospital equipment used by HCWs, which exposes them to a higher risk of inhalation of infected aerosols.

Most studies considered in this review showed a higher prevalence of antibodies in HCWs, except for two studies, one conducted in the United Kingdom,[22] and the other in the United States.[23]

A systematic review,[27] focused exclusively on dental HCWs, showed a higher prevalence of antibodies in this population but concluded that there is limited evidence of occupational risk for legionella infection to dental HCWs.

A limitation of this meta-analysis is that all the studies include are observational studies, which involve several biases. Exposure assessment for cases and controls was problematic because (1) water sampling was not always carried out in the studies; therefore it was not always possible to establish the actual presence of exposure at risk; and (2) the nature of the outcome taken into consideration (i.e. seroprevalence) does not allow the establishment of when and where the contact took place. A further limitation lies in the definition of 'healthcare workers'. This term excludes maintenance, food service and janitorial staff, who may be exposed to the same sources of legionella infection as the HCWs with clinical responsibilities/patient contact, thus not allowing a comprehensive view of the problem. In addition, hospital staff that are not included in the HCW category are often more likely to be socioeconomically disadvantaged, have a lower level of education and experience greater health disparities in terms of access to quality healthcare, proper diagnosis and treatment.

The purpose of the review was to establish whether legionellosis is an occupational risk for HCWs. The importance and relevance of the topic are demonstrated by the consultation of the surveillance systems with the focus on 'legionellosis', which shows an increasing trend in cases of legionellosis in the United States and Europe.[28] An increasing trend in notifications of cases of legionellosis has also been confirmed in Italy. According to the national epidemiological bulletin 2020, the incidence of legionellosis in 2019 was equal to 52.9 cases per million inhabitants, a slight increase compared with the previous year (48.9 per million). However, this is a considerable increase compared with 2016, for example, where the incidence was 28.2 per million inhabitants and in which there had already been a significant increase compared with the previous years.[3]

Seroprevalence studies also aim to gain a better understanding of the spread of legionella. The risk of exposure has always been underestimated because the bacterium is difficult to isolate from physiological samples and in the workplace. In addition, legionella infections can be asymptomatic or, if symptomatic, clinically indistinguishable from other pneumonia.[29] The results of the meta-analysis are not sufficient to fully understand the spread of legionella.

Despite the results of the present meta-analysis and support for the use of these criteria, it is not possible to estimate whether HCWs have an elevated risk of infection because of the limitations described here, especially considering that increased seropositivity is not linked to an increased risk of infection resulting in illness.

Sensitivity analysis, which considered studies published before and after 2000 separately, showed a higher OR in older studies and a higher risk for HCWs during that period. This could be a consequence of the introduction of measures to control the risk of exposure in the workplace since 2000, including identification of systems that may favour the development of the bacterium, further awareness-raising, increased training of operators, increase of the information and greater control of legionella in water systems (by requesting a consultation with specialised engineers or treatment providers and taking measures to control such as increasing water temperature or use of biocides), and finally, monitoring to control the growth of total aerobic bacteria and legionella.[32,33]

In some countries, exposure to occupational disease is an accepted risk because of the work of the employee, even if the occupational disease itself is caused by a gradual, progressive and slow action of the risks present at the workplace.

In Italy, as a result of Judgments No. 179 of 10 February 1988 and No. 206 of 11 February 1988 of the Court constitutional, a mixed system was introduced that provides both the existence of diseases for which there is a legal presumption about their occupational origin and also the possibility for the worker to demonstrate (by an ordinary form of evidence) the occupational origin of diseases not tabulated (or caused from work not provided for in the tables) or that manifest beyond the maximum period of indemnity established by the tables. In this context, the importance of the studies and meta-analysis is evident; the results may influence the political choices of the Legislator regarding the extension or not of tables or impose remediation policies if the pathology is not considered work related from an epidemiological point of view.

The higher seroprevalence of legionella in HCWs shown in this review, coupled with the increased risk of exposure to this microorganism, and the possible severity of the related disease highlight the need for further study to establish if legionellosis is a real risk for HCWs.

Author statements

Ethical approval

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Competing interests

None declared.

Authors' contributions

G.L.T. contributed to conceptualisation and methodology. A.B., V.C., and G.L.T. contributed to formal analysis. A.B. and V.C. contributed to investigation, data curation, and writing the original article. A.B. and G.L.T. reviewed and edited the article. A.M., A.D.C., M.D.G., and G.L.T. contributed to supervision. All authors have read and agreed to the published version of the article.

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Original Research

Conspiracy mentality and health-related behaviour during the COVID-19 pandemic: a multiwave survey in Italy

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ABSTRACT

Objectives: This study aimed to (1) explore the changes in conspiracy mentality across the four waves of the COVID-19 pandemic; (2) assess the relationship between conspirative mentality and psychological/behavioural variables; (3) identify the predictors of conspirative mentality; and (4) explore the effect of conspirative mentality on COVID-19 protective behaviour.
Study design: This was a multiwave survey.
Methods: A total of 10,013 Italian individuals, aged 18–70 years, were assessed across the four waves (from January to May 2021) through online survey. We collected information about the sociodemographic characteristics of participants, personal experiences of COVID-19 infection, trust, COVID-19 protective behaviours, COVID-19 risk perception, arousal, auto-efficacy, resilience and well-being. Conspiracy mentality was assessed with the Conspiracy Mentality Questionnaire. The statistical analyses included exploratory factorial analyses, Pearson correlations and multiple linear regressions.
Results: The conspiracy mentality score during the COVID-19 pandemic was medium–high (mean 59.0 on a 0–100 scale) and slightly increased from 58.2 to 59.9 across months, in parallel with a slight decrease in trust in health institutions and scientific informational sources. Individuals aged >35 years, poorly educated and particularly scared about their financial situation were at risk of showing higher levels of conspirative mentality. Higher levels of conspirative mentality were risk factors for low levels of COVID-19 protective behaviours.
Conclusions: Clear and effective communication may improve trust in health institutions and informational sources, decrease conspirative theories and increase compliance with protective behaviour.

Introduction

The COVID-19 pandemic has caused an enormous number of deaths and human suffering worldwide, posing extraordinary challenges to public health. Italy was the first European country to suffer severe effects of the virus spread,[1] with a spiral of infections that placed it at the top of the international rankings. In this context, a range of conspiracy theories emerged in many countries, for example, the virus was purposively created in the laboratory, the virus was a hoax or a bioweapon, secret activities or organisations exist, COVID-19 vaccines had been developed before the pandemic, and the effects of the treatments (including vaccines) have not been disclosed. For example, a survey conducted with adults in the United States found that about 50% reported that they

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believed the virus was either probably or definitely intentionally created or accidentally released by China.[2] The onset and maintenance of conspiracy theories in facing uncertain and complex events such as the COVID-19 pandemic may be explained by the fact that theories and beliefs about such events grant individuals an illusion of control, which acts as palliative compensation for the lack of real control.[3,4]

Conspiracy beliefs are particularly noteworthy in the current pandemic. They appear to be pervasive across time[5] and tend to undermine any action against the conspiracy theories, in part because they are not easy to rebut.[6] Conspiracy theories play a potentially damaging role in decreasing trust in authorities and institutions[7,8] and in shaping health-related behaviour, acting as barriers to compliance with health protective behaviour such as poor adherence to medication regimens, resistance to preventive action and unwillingness to vaccinate.[9–13] Several studies aimed at clarifying the association between conspiracy theories and health-related behaviour have shown that these theories can have negative impacts. For example, HIV conspiracy theories lead to negative attitudes toward HIV medication,[14,15] and anti-vaccine conspiracy theories reduce the willingness of parents to vaccinate their children.[9] Similar effects are expected during the COVID-19 pandemic.

Studies published in 2020 and 2021 on conspiracy beliefs and COVID-19 found that conspiracy mentality seems to be inversely related to a variety of factors such as educational level, threat perception of the pandemic, various preventive actions, perceived safety of vaccination, intention to be vaccinated against COVID-19, intention to take diagnostic or antibody tests, trust in different agencies and governments (e.g. media, health care, public health institutions, science) and adherence to public health experts' warnings or official recommendations.[4,5,13,16–21]

Owing to the important impact of conspiracy mentality on several behavioural domains, it is crucial to investigate how it evolved with the progression of the COVID-19 pandemic, its association with other behavioural and psychological variables and its predictors. Therefore, the aims of our study were to (1) explore the changes in conspiracy mentality during four different periods of the COVID-19 pandemic in a large, representative sample of the Italian population; (2) assess the relationship between conspirative mentality and psychological and behavioural variables (e.g. trust, resilience, risk perception, auto-efficacy and arousal); (3) identify the sociodemographic and COVID-19–related experience predictors of conspirative mentality; and (4) explore the effect of conspirative mentality on COVID-19 protective behaviour.

Methods

Participants and procedures

This study is part of the larger project promoted by the World Health Organisation (WHO), "*Monitoring knowledge, risk perceptions, preventive behaviours and trust to inform pandemic outbreak response*" and carried out in over 30 countries of the WHO European Region (Registered ISRCTN on 11/05/2021, ID: ISRCTN26200758).

In Italy, the survey was conducted by administering an online questionnaire developed *ad hoc* by the WHO (January–May 2021) to 10,013 individuals aged 18–70 years across the four waves of the pandemic, with approximately 2500 participants for each wave.[22–24] The four sample groups were selected using the same stratification method; they were equally representative of the Italian population and were therefore homogeneous and comparable. Therefore, in this manuscript, we henceforth use the term "sample" to refer to the four sample groups interviewed in the four waves.

A detailed sampling plan was developed to obtain a representative sample of the Italian adult population (for details, see https://doi.org/10.1186/ISRCTN26200758). The interviews were conducted using Doxa S.p.a. and carried out with the computer-assisted web interviewing technique on an online panel and on the Confirmit software platform used by Doxa S.p.a. The average administration time was approximately 18–20 min.

Measures

The WHO questionnaire included 21 thematic areas noteworthy for the investigation of the COVID-19 experience. The questionnaire was translated into the desired country language by the designated recruiting sites following the WHO guidelines for translations of study tools. The process included the following steps: forward translation, panel experts, back-translation, pretest and cognitive interviews and development of the final version.

In this article, we considered the following areas explored in the WHO survey:

- Sociodemographic characteristics (e.g. age, sex, education, rural/urban residence, financial situation, work status); personal experience of COVID-19 infection; trust in information sources (e.g. television, newspapers, health workers, social media, radio, Ministry of Health, Institute of Public Health, hotlines, official websites, celebrities, etc.); attitudes toward COVID-19 protective behaviours (hygiene, social behaviour, mask use, respecting social distancing protocol); COVID-19 risk perception; arousal; and auto-efficacy.
- The three items of the *Brief Resilience Scale*,[25] ranged from 1 (*strongly disagree*) to 7 (*strongly agree*). Higher scores indicated higher resilience.
- The *Conspiracy Mentality Questionnaire*,[26] an instrument composed of five items to assess generic beliefs in conspiracy theories, ranged from 1 (*certainly not true*) to 7 (*certainly true*). Higher scores indicated a higher conspiracy mentality.
- The *WHO 5-item well-being scale (WHO-5):* a measure of well-being composed of five items, ranged from 1 (*at no time*) to 6 (*all of the time*).[27] The overall score ranged from 0 to 100. A score $\leq$50 indicated poor psychological well-being, suggesting further investigation into possible symptoms of depression. A score $\leq$28 or below was indicative of clinical depression.

Statistical analyses

We performed nine different explorative factorial analyses on the respondents' scores of items that revealed the psychological (cognitive and emotional) and behavioural patterns of the interviewees: conspiracy mentality, risk perception, arousal, auto-efficacy, protective behaviours, trust in media information sources, trust in health information sources, frequency of use of media information sources, frequency of use of health information sources, trust in health institutions and resilience, for each of the four waves, separately. These items are listed in Table 1S. Metric invariance among the waves was computed for each pattern. Because no significant difference was observed among the waves, explorative factorial analyses were performed on the four waves combined, and a single factor was estimated for each pattern. The factorial scores of each pattern were then transformed to assume values from 0 to 100 for better interpretation and were used in all subsequent analyses.

Categorical data were summarised as absolute and percentage frequencies, whereas quantitative data (normalised factorial scores) were presented as means and standard deviations.

Differences among waves in the distribution of categorical variables were assessed using the Chi-squared test, whereas differences in the mean values of quantitative variables were assessed using analysis of variance, followed by multiple comparisons corrected by the Bonferroni's method.

Pairwise correlations between behavioural and psychological scores were computed using the Pearson correlation coefficient.

A multiple linear regression was performed using the conspiracy index (normalised to 0–100) as the dependent variable and the following variables as independent variables: sex, age, education, occupation, presence of chronic diseases, area of residence, rural/urban zone, concerns about their own economic situation (due to the pandemic), having had COVID-19 (self) and knowing someone who was infected with COVID-19. Regression unstandardised coefficients (b) with 95% confidence intervals were calculated for each independent variable. All regression models were computed for each wave separately and for all waves combined (adjusting for waves). The heterogeneity statistic I^2 was computed to assess the heterogeneity of the estimated coefficients among waves. An I^2 value greater than 60% was considered indicative of substantial heterogeneity. The same multiple linear regressions were also performed, considering the protective behaviours index (transformed to a 0–100 scale) as the dependent variable and adding the conspiracy index (transformed to a 0–100 scale) to the independent variables listed above. Regression models' goodness-of-fit was calculated using the R^2 statistics. Regression models were built based on clinical considerations, on an accurate literature screening and findings of previous studies and on the availability of data included in the WHO questionnaire. All analyses were performed using STATA 16 based on the statistical weights provided by the DOXA.

Results

Sociodemographic, behavioural and psychological characteristics of the sample across the four waves

Table 1 shows the weighted absolute numbers and percentages of the sociodemographic and health variables of the study sample across the four waves. Sex, age, occupation, area of residence and rural/urban area were used as stratifying factors in the sampling strategy; hence, their distributions did not differ across the four waves. The percentage of participants infected with COVID-19 significantly increased from 5.7% in the first wave (mild: 5.4%; severe: 0.3%) to 9.3% in the fourth wave (mild: 8.2%; severe: 1.1%). Regarding concerns about their own economic situation due to the pandemic, the percentage of individuals who were not worried significantly increased from 11.5% in the first wave to 17.4% in the fourth.

Table 2 presents behavioural and psychological factorial scores across the four waves. The conspiracy score slightly increased over time, with a significant difference between waves 1 (58.20 ± 23.41) and 4 (59.90 ± 24.24). The highest level of trust in scientific information sources and health institutions and the highest use of scientific information sources were reached in wave 2, which showed significant differences compared with waves 3 and 4. The use of informal information sources decreased over time, with the only significant difference being between waves 1 and 4.

Correlations between conspirative mentality and psychological and behavioural aspects

The pairwise correlations between the conspiracy mentality factor and all other variables considered here (e.g. risk perception, arousal, auto-efficacy, protective behaviour, trust in informal information sources, trust in scientific information sources, trust in scientific institutions, resilience and WHO-5 score) are presented in Table 2S. We considered only correlations with absolute values above or equal to 0.2. Conspiracy mentality was negatively correlated with trust in scientific information, either when considering all waves together ($r = -0.31$) or separately in the four waves (wave 1, $r = -0.37$; wave 2, $r = -0.30$; wave 3, $r = -0.32$; and wave 4, $r = .0.25$). Conspiracy mentality was also negatively correlated with trust in health institutions in the overall group ($r = -0.28$) and in the four waves (wave 1, $r = -0.32$; wave 2, $r = -0.27$; wave 3, $r = -0.29$; and wave 4, $r = -0.21$).

Predictors of conspirative mentality

The results of the multiple regression analysis are presented in Table 3. No heterogeneity was found among waves (I^2 <60% for all predictors). The conspiracy index was higher in older (>35 years) and less-educated people. Being worried about the economic situation due to COVID-19 is associated with higher ratings on the conspiracy index, as well as not knowing about contracting the disease with respect to not having contracted it. Knowing someone who was infected with COVID-19 was associated with a decrease in conspiracy mentality levels. In terms of differences across the four waves, conspiracy mentality ratings increased significantly in the fourth wave compared with the first. We replicated the models for every wave, and the results were similar, merging all waves, with only a few exceptions: not knowing about having contracted the disease with respect to not having contracted it. This factor was not significant in any of the waves, although it was consistent with respect to direction and size across the four waves. In wave 3, people living in rural settings had a higher conspiracy index than those in urban settings, and subjects who did not suffer from any chronic illness had a lower conspiracy mentality index compared with those who reported suffering from at least one. In most other cases, the results for every wave individually do not reach statistical significance, although they are of the same magnitude and direction.

Predictors of protective behaviour

All predictors, apart from age (35–44 years) and occupation (being a health professional), were homogenous among the waves ($I^2 = 78\%$ and 77%, respectively). Women, older subjects (35 years and above), having a greater number of worries about the economic situation, and people who knew someone who died of COVID-19 reported higher levels of protective behaviour. Conversely, people who declared not to know if they had ever been infected or to have had a mild infection did not work in the health sector and did not have or did not know of having any chronic disease reported lower levels of protective behaviours. Finally, a slightly higher conspiracy normalised score was associated with lower levels of protective behaviours across all waves, with the exception of wave 3 (Table 4).

Discussion

Is there any consistent profile of individuals showing a 'conspirative' mentality?

We found that higher levels of conspirative mentality were associated with lower trust in scientific information sources and healthcare institutions. Furthermore, in our survey, conspirative mentality was associated with older age, lower education levels and greater number of worries about economic difficulties. Interestingly, individuals with the highest levels of conspirative beliefs were also the least likely to have personally known people who were directly infected by the SARS-CoV-2 virus or who died due to the infection.

Table 1
Sociodemographic characteristics and COVID-19 personal experience of the Italian general population (n = 10,013).

Characteristics	Wave 1		Wave 2		Wave 3		Wave 4		Total		χ^2 *P*
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	
Sex											ns
Male	1244	49.7%	1243	49.7%	1245	49.7%	1242	49.7%	4974	49.7%	
Female	1260	50.3%	1259	50.3%	1262	50.3%	1258	50.3%	5039	50.3%	
Age (years)											ns
18–34	652	26.0%	652	26.0%	653	26.0%	651	26.0%	2607	26.0%	
35–44	481	19.2%	480	19.2%	481	19.2%	480	19.2%	1923	19.2%	
45–54	594	23.7%	594	23.7%	595	23.7%	594	23.7%	2377	23.7%	
55–70	777	31.0%	776	31.0%	778	31.0%	775	31.0%	3106	31.0%	
Educational level (years)											**<0.0001**
0–8 years	1027	41.0%	1026	41.0%	1028	41.0%	1025	41.0%	4105	41.0%	
9–13 years	772	30.8%	832	33.2%	891	35.5%	1013	40.5%	3507	35.0%	
>13 years	705	28.2%	645	25.8%	588	23.5%	462	18.5%	2400	24.0%	
Occupational status											0.16
Employed (not health sector)	1216	48.6%	1198	47.9%	1213	48.4%	1237	49.5%	4864	48.6%	
Employed (health sector)	93	3.7%	111	4.4%	98	3.9%	71	2.8%	373	3.7%	
Unemployed	1194	47.7%	1193	47.7%	1196	47.7%	1193	47.7%	4776	47.7%	
Chronic illness											**0.0007**
None	1869	74.7%	1890	75.5%	1841	73.4%	1810	72.4%	7411	74.0%	
Yes	548	21.9%	530	21.2%	544	21.7%	549	22.0%	2171	21.7%	
Do not know	86	3.5%	83	3.3%	122	4.9%	141	5.6%	431	4.3%	
Rural/urban area											ns
Rural	1920	76.7%	1918	76.7%	1922	76.7%	1917	76.7%	7677	76.7%	
Urban	584	23.3%	584	23.3%	585	23.3%	583	23.3%	2336	23.3%	
Italian region											
North-West	662	26.5%	662	26.5%	663	26.5%	661	26.5%	2649	26.5%	
North-East	480	19.2%	480	19.2%	481	19.2%	480	19.2%	1921	19.2%	
Centre	497	19.8%	496	19.8%	497	19.8%	496	19.8%	1985	19.8%	
South/Islands	865	34.5%	864	34.5%	866	34.5%	863	34.5%	3458	34.5%	
Concerns about their own economic situation											**<0.0001**
Absolutely not	49	2.0%	60	2.4%	52	2.1%	68	2.7%	230	2.3%	
Not	93	3.7%	78	3.1%	93	3.7%	107	4.3%	371	3.7%	
Partially not	145	5.8%	125	5.0%	169	6.7%	261	10.4%	700	7.0%	
Neither not nor yes	655	26.1%	647	25.9%	612	24.4%	577	23.1%	2491	24.9%	
Partially yes	685	27.4%	711	28.4%	722	28.8%	749	30.0%	2868	28.6%	
Yes	346	13.8%	367	14.7%	332	13.2%	353	14.1%	1397	14.0%	
Absolutely yes	531	21.2%	512	20.5%	527	21.0%	386	15.4%	1956	19.5%	
COVID-19 (self)											**<0.0001**
Do not know	233	9.3%	230	9.2%	191	7.6%	193	7.7%	847	8.5%	
No	2129	85.0%	2078	83.1%	2134	85.1%	2076	83.0%	8417	84.1%	
Yes, mild	136	5.4%	175	7.0%	158	6.3%	204	8.2%	673	6.7%	
Yes, severe	6	0.3%	19	0.8%	24	0.9%	27	1.1%	76	0.8%	
COVID-19 (others)											**0.015**
No	715	28.5%	687	27.5%	671	26.7%	666	26.6%	2738	27.3%	
Yes, alive	821	32.8%	767	30.7%	774	30.9%	862	34.5%	3224	32.2%	
Yes, deceased	969	38.7%	1048	41.9%	1062	42.4%	972	38.9%	4051	40.5%	

Table 2
Behavioural and psychological scores across the four waves in Italian general population (n = 10,013).

Factorial scores	Wave 1		Wave 2		Wave 3		Wave 4		TOT		P	W1 vs W2	W1 vs W3	W1 vs W4	W2 vs W3	W2 vs W4	W3 vs W4
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD							
Conspiracy	58.20	23.41	58.66	26.04	59.35	22.16	59.90	24.24	59.03	24.01	**0.0127**	–	–	*	–	–	–
Risk perception	56.71	18.17	56.63	19.96	56.18	17.20	55.68	20.01	56.30	18.87	**0.0406**	–	–	–	–	–	–
Arousal	63.38	28.50	64.14	31.09	63.92	27.54	59.97	31.91	62.86	29.86	**<0.0001**	–	–	**	–	**	**
Auto-efficacy	59.16	17.89	59.33	20.62	59.64	18.08	60.46	20.89	59.65	19.42	**0.0054**	–	–	**	–	*	–
Protective behaviours	81.41	23.18	81.79	25.67	81.32	21.70	80.52	26.85	81.26	24.43	**0.0469**	–	–	–	–	*	–
Trust in informal information sources	43.21	21.64	43.59	22.99	42.73	21.07	42.51	22.87	43.01	22.15	0.2028	–	–	–	–	–	–
Trust in scientific information sources	64.02	25.00	65.21	26.30	62.86	24.38	63.08	27.31	63.79	25.78	**0.0002**	–	–	–	**	**	–
Use of sources of informal information sources	36.07	21.14	35.97	22.54	35.42	21.28	34.56	23.06	35.51	22.02	**0.0270**	–	–	*	–	–	–
Use of sources of scientific information sources	47.70	25.49	49.66	26.24	46.35	25.45	46.53	27.33	47.56	26.17	**<0.0001**	*	–	–	**	**	–
Trust in health institutions	61.71	24.08	62.34	25.94	60.41	23.97	60.49	25.95	61.24	25.01	**0.0012**	–	–	–	**	**	–
Resilience	50.29	23.09	49.78	25.69	49.32	22.82	49.17	24.60	49.64	24.08	0.2294	–	–	–	–	–	–

P-values in bold are significant at 0.05 level, *p-value for pairwise comparisons <0.05, ** p-value for pairwise comparisons <0.01.

Our results are in line with previous studies that identified how a higher conspirative mentality was associated with low educational levels[28,29] and low trust in governments and aided institutions (e.g. media, health care, public health institutions) or in science and scientists.[30–32]

According to the literature, conspiracy theories might be used by more psychologically vulnerable individuals to cope with uncertain and complex events, such as the COVID-19 pandemic, to attain an illusion of control, which may act as palliative compensation for the lack of real control.[3,4] Moreover, the fact that more individuals with conspirative mentalities were more likely to not know people who were infected by or died because of the SARS-CoV-2 virus may be explained by the fact that the personal experience of this disease may reduce the conspirative belief that the pandemic was either not real or magnified by media or institutions.

Conspiracy mentality increased while trust in Health Institutions and scientific information sources decreased during the progression of the COVID-19 pandemic

Our findings show that the conspiracy mentality in an Italian representative sample was at a medium–high level and increased slightly from January to May 2021. Simultaneously, trust in health institutions and scientific information sources decreased. This maladaptive trend of the conspirative mentality is particularly important if we consider its potentially damaging role in influencing health-related behaviours, acting as barriers to satisfactory compliance with health protective behaviours[9–13] or containment-related behaviours.[33] This result is somewhat different from the finding of another study[5] in which the authors found a stability of conspiracy beliefs during the early phases of the COVID-19 pandemic. In any event, it should be emphasised that the differences found, albeit statistically significant, were small in magnitude, and the implications remain to be ascertained.

The result that higher conspirative mentality across time was accompanied by a decline in trust in healthcare institutions is in line with previous studies.[7,8] However, due to the cross-sectional nature of our survey, we were unable to investigate any causal associations between conspirative mentality and trust. We may hypothesise that some public health decisions (e.g. lockdown and restriction measures, vaccination campaigns, promotion of social distancing) taken during the COVID-19 pandemic may have progressively impaired trust in official institutions and related information sources and may have amplified the conspirative mentality. In particular, the decisions that may have triggered this change may have included containment measures to reduce the spread of the contagion, the perceived lack of economic and social support to families and the perceived absence of strong and transparent communicative messages about vaccines (in particular with reference to the AstraZeneca vaccine). In fact, in Italy, from January to May 2021, there was a massive spread of information (including fake information) about vaccines, and this included numerous controversial issues regarding the AstraZeneca vaccine. This situation may have fuelled the conspirative mentality that affected trust in institutions.

Conspirative mentality affects COVID-19 protective behaviour

We found that lower levels of conspirative mentality, together with sociodemographic and clinical variables such as being women, being older than 35 years, being unoccupied, having a chronic illness, being worried about the economic situation, not having had the COVID-19 infection and knowing someone

Table 3
Multiple regression analyses on conspiracy normalised score.

Independent variables	Waves 1 + 2 + 3 + 4			Wave 1			Wave 2			Wave 3			Wave 4		
	N	10,013		*N*	2504		*N*	2502		*N*	2507		*N*	2500	
	F(28,9984)	25.040		*F*(25,2478)	7.670		*F*(25,2476)	6.040		*F*(25,2481)	10.430		*F*(25,2474)	7.790	
	P (F)	<0.001		*P* (F)	<0.001		*P* (F)	<0.001		*P* (F)	<0.001		*P* (F)	<0.001	
	R-squared	0.073		R-squared	0.074		R-squared	0.066		R-squared	0.094		R-squared	0.085	
	Coeff[a]	95% CI l	95% CI u	Coeff[a]	95% CI l	95% CI u	Coeff[a]	95% CI l	95% CI u	Coeff[a]	95% CI l	95% CI u	Coeff[a]	95% CI l	95% CI u
Sex															
Females vs males	−0.017	−0.797	0.764	0.230	−1.413	1.873	−0.736	−2.350	0.878	−0.624	−2.234	0.985	0.973	−0.501	2.446
Age (years)															
35–44 vs 18–34 years	**2.954**	**1.772**	**4.135**	**3.042**	**0.578**	**5.506**	**2.770**	**0.196**	**5.344**	**4.678**	**2.463**	**6.893**	1.005	−1.324	3.334
45–54 vs 18–34 years	**2.475**	**1.321**	**3.629**	2.181	−0.157	4.519	1.258	−1.291	3.807	**3.524**	**1.254**	**5.794**	**2.468**	**0.220**	**4.715**
55–70 vs 18–34 years	**3.048**	**1.973**	**4.123**	**2.920**	**0.707**	**5.133**	**2.392**	**0.180**	**4.604**	**4.100**	**1.941**	**6.259**	**2.705**	**0.630**	**4.780**
Educational level (years)															
9–13 vs 0–8 years	−0.578	−1.474	0.318	−1.386	−3.301	0.529	−0.636	−2.618	1.347	−1.010	−2.825	0.805	0.189	−1.491	1.869
>13 vs 0–8 years	**−4.343**	**−5.395**	**−3.292**	**−4.147**	**−6.270**	**−2.025**	**−6.040**	**−8.327**	**−3.754**	**−4.374**	**−6.497**	**−2.251**	**−3.531**	**−5.617**	**−1.444**
Occupational status															
Yes (not health sector) vs No	0.144	−0.679	0.967	0.679	−1.086	2.443	0.386	−1.304	2.076	−0.628	−2.264	1.008	0.215	−1.409	1.839
Yes (health sector) vs No	−1.515	−3.751	0.722	−1.988	−5.842	1.865	−0.467	−5.052	4.118	1.050	−3.200	5.300	**−6.039**	**−10.992**	**−1.086**
Chronic illness															
No vs Yes	−0.866	−1.839	0.107	0.116	−1.869	2.100	−1.016	−3.082	1.051	**−2.322**	**−4.209**	**−0.434**	−0.097	−1.930	1.736
Do not know vs Yes	0.131	−1.815	2.077	2.501	−2.145	7.148	−2.646	−6.993	1.701	−0.676	−4.328	2.977	1.360	−1.968	4.688
Geographical area															
North-West vs Centre	−1.012	−2.206	0.182	−0.217	−2.701	2.266	−0.705	−3.150	1.741	−1.482	−3.781	0.816	−1.262	−3.623	1.100
North-East vs Centre	0.982	−0.162	2.126	**2.727**	**0.464**	**4.990**	1.962	−0.426	4.350	0.065	−2.228	2.358	−1.004	−3.208	1.201
South/Islands vs Centre	0.298	−0.712	1.307	0.794	−1.263	2.851	0.669	−1.426	2.764	−1.032	−3.056	0.991	0.944	−0.978	2.865
Rural/urban area															
Rural vs urban	0.652	−0.264	1.569	0.159	−1.740	2.057	1.359	−0.556	3.274	**2.107**	**0.321**	**3.893**	−0.589	−2.462	1.284
Concerns about their own economic situation															
Absolutely not vs neither not nor yes	−2.586	−6.224	1.052	−0.559	−8.939	7.821	−2.424	−9.079	4.230	−2.226	−8.822	4.370	−3.692	−10.988	3.604
Not vs neither not nor yes	−1.192	−3.657	1.272	−1.586	−6.468	3.295	−1.859	−7.761	4.043	3.532	−1.380	8.443	−4.013	−8.122	0.097
Partially not vs neither not nor yes	−1.441	−3.027	0.144	1.211	−2.218	4.640	−0.899	−4.799	3.001	−1.542	−4.552	1.468	**−3.228**	**−5.925**	**−0.532**
Partially yes vs neither not nor yes	**2.915**	**1.944**	**3.886**	**3.478**	**1.473**	**5.484**	**2.893**	**0.884**	**4.902**	**2.248**	**0.237**	**4.258**	**3.089**	**1.297**	**4.882**
Yes vs not vs neither not nor yes	**5.995**	**4.729**	**7.260**	**8.110**	**5.562**	**10.659**	**4.283**	**1.634**	**6.932**	**6.097**	**3.531**	**8.663**	**5.642**	**3.257**	**8.027**
Absolutely yes vs neither not nor yes	**11.295**	**10.090**	**12.499**	**11.804**	**9.399**	**14.209**	**9.575**	**7.207**	**11.943**	**12.256**	**9.874**	**14.638**	**11.726**	**9.178**	**14.274**
Having had COVID-19															
Do not know vs No	**1.622**	**0.289**	**2.956**	1.269	−1.411	3.949	1.048	−1.784	3.880	1.988	−0.684	4.660	2.291	−0.159	4.740
Yes, mild vs No	0.288	−1.302	1.877	1.504	−1.816	4.823	1.794	−1.635	5.223	−0.150	−3.269	2.970	−1.206	−3.987	1.574
Yes, severe vs No	3.383	−1.460	8.227	5.617	−6.287	17.521	1.367	−12.497	15.230	4.222	−3.024	11.469	3.541	−2.748	9.831
Knowing people who had COVID-19															
Yes, alive vs No	**−2.856**	**−3.849**	**−1.863**	**−3.168**	**−5.217**	**−1.118**	**−2.982**	**−5.005**	**−0.958**	**−3.408**	**−5.390**	**−1.427**	**−2.060**	**−3.976**	**−0.143**
Yes, deceased vs No	**−2.374**	**−3.333**	**−1.416**	**−1.985**	**−3.962**	**−0.009**	**−2.415**	**−4.326**	**−0.505**	**−3.348**	**−5.270**	**−1.426**	**−1.939**	**−3.796**	**−0.082**
Wave															
Wave 2 vs Wave 1	0.371	−0.738	1.480												
Wave 3 vs Wave 1	1.023	−0.066	2.111												
Wave 4 vs Wave 1	**1.994**	**0.920**	**3.068**												
Constant	55.388	53.390	57.385	53.388	49.650	57.125	56.847	52.923	60.771	57.341	53.605	61.078	57.424	53.741	61.108

P-values in bold are significant at 0.05 level.
[a] Unstandardised coefficients.

Table 4
Multiple regression analyses on protective behaviours normalised score.

Independent variables	Waves 1 + 2+3 + 4			Wave 1			Wave 2			Wave 3			Wave 4		
	N	10,013		*N*	2504		*N*	2502		*N*	2507		*N*	2500	
	F(29,9983)	25.280		*F*(26,2477)	8.910		*F*(26,2475)	8.210		*F*(26,2480)	8.150		*F*(26,2473)	6.400	
	P (F)	<0.001		*P* (F)	<0.001		*P* (F)	<0.001		*P* (F)	<0.001		*P* (F)	<0.001	
	R-squared	0.072		R-squared	0.087		R-squared	0.083		R-squared	0.080		R-squared	0.076	
	Coeff[a]	95%CI l	95%CI u	Coeff[a]	95%CI l	95%CI u	Coeff[a]	95%CI l	95%CI u	Coeff[a]	95%CI l	95%CI u	Coeff[a]	95%CI l	95%CI u
Conspiracy normalised score	**−0.033**	**−0.051**	**−0.014**	**−0.050**	**−0.088**	**−0.013**	**−0.035**	**−0.068**	**−0.001**	−0.009	−0.046	0.028	**−0.044**	**−0.087**	**0.000**
Sex															
Females vs males	**5.597**	**4.952**	**6.241**	**5.697**	**4.403**	**6.991**	**5.402**	**4.170**	**6.633**	**6.510**	**5.207**	**7.814**	**4.642**	**3.290**	**5.993**
Age (years)															
35−44 vs 18−34 years	**1.324**	**0.279**	**2.369**	0.998	−1.086	3.082	**2.770**	**0.720**	**4.819**	**2.772**	**0.793**	**4.750**	−2.214	−4.516	0.089
45−54 vs 18−34 years	**2.412**	**1.454**	**3.371**	1.173	−0.702	3.048	**3.046**	**1.051**	**5.040**	**2.383**	**0.518**	**4.249**	1.822	−0.197	3.840
55−70 vs 18−34 years	**3.087**	**2.199**	**3.975**	**2.047**	**0.266**	**3.827**	**3.838**	**2.058**	**5.618**	**2.930**	**1.205**	**4.656**	**3.134**	**1.267**	**5.001**
Educational level (years)															
9−13 vs 0−8 years	0.335	−0.411	1.082	−0.966	−2.502	0.569	−0.068	−1.566	1.430	1.191	−0.318	2.700	1.208	−0.329	2.746
>13 vs 0−8 years	0.043	−0.833	0.919	−1.077	−2.737	0.582	0.332	−1.398	2.063	−0.238	−2.029	1.554	1.290	−0.646	3.226
Occupational status															
Yes (not health sector) vs No	**−0.838**	**−1.519**	**−0.158**	−1.145	−2.495	0.204	−0.924	−2.216	0.368	−0.355	−1.724	1.014	0.090	−1.405	1.585
Yes (health sector) vs No	−0.185	−1.975	1.605	2.226	−0.923	5.376	−0.169	−3.335	2.997	2.655	−0.287	5.597	**−6.699**	**−11.913**	**−1.485**
Chronic illness															
No vs Yes	**−0.890**	**−1.648**	**−0.131**	**−1.957**	**−3.399**	**−0.515**	0.318	−1.164	1.800	−1.108	−2.645	0.429	−0.917	−2.525	0.692
Do not know vs Yes	**−4.378**	**−6.166**	**−2.590**	**−5.207**	**−9.175**	**−1.240**	−3.123	−6.343	0.097	**−5.276**	**−8.708**	**−1.843**	−3.136	−6.536	0.264
Geographical area															
North-West vs Centre	**1.139**	**0.165**	**2.113**	1.157	−0.778	3.092	0.137	−1.760	2.034	1.344	−0.566	3.254	1.882	−0.185	3.950
North-East vs Centre	−0.024	−1.011	0.963	0.247	−1.666	2.159	0.804	−1.071	2.680	0.298	−1.639	2.234	−1.563	−3.724	0.598
South/Islands vs centre	**2.566**	**1.717**	**3.415**	**3.255**	**1.594**	**4.916**	**3.112**	**1.515**	**4.708**	**1.784**	**0.062**	**3.507**	**2.085**	**0.232**	**3.937**
Rural/urban area															
Rural vs urban	0.037	−0.721	0.794	0.878	−0.664	2.420	−0.015	−1.488	1.458	−1.041	−2.493	0.411	0.988	−0.673	2.650
Concerns about their own economic situation															
Absolutely not vs neither not nor yes	**−5.015**	**−8.227**	**−1.803**	−0.511	−7.031	6.008	−3.853	−9.820	2.115	−5.048	−11.105	1.008	**−8.684**	**−15.152**	**−2.217**
Not vs neither not nor yes	−0.568	−2.334	1.199	−1.733	−5.669	2.203	0.588	−3.214	4.390	0.004	−3.039	3.046	−1.013	−4.330	2.304
Partially not vs neither not nor yes	**−2.827**	**−4.260**	**−1.394**	−2.428	−5.380	0.524	−2.221	−5.060	0.618	−2.680	−5.596	0.235	**−3.393**	**−6.096**	**−0.691**
Partially yes vs neither not nor yes	0.311	−0.539	1.161	1.185	−0.495	2.864	0.407	−1.203	2.017	−0.294	−2.046	1.458	0.185	−1.605	1.975
Yes vs not vs neither not nor yes	**2.392**	**1.354**	**3.430**	**3.402**	**1.266**	**5.539**	**2.108**	**0.090**	**4.126**	**2.185**	**0.128**	**4.243**	**2.226**	**0.103**	**4.348**
Absolutely yes vs neither not nor yes	**3.174**	**2.184**	**4.165**	**4.000**	**2.135**	**5.865**	**4.485**	**2.662**	**6.307**	**2.154**	**0.182**	**4.126**	2.110	−0.256	4.477
Having had COVID-19															
Do not know vs No	**−3.971**	**−5.198**	**−2.744**	**−4.658**	**−6.936**	**−2.380**	**−3.799**	**−6.004**	**−1.595**	**−2.653**	**−5.157**	**−0.150**	**−3.882**	**−6.758**	**−1.006**
Yes, mild vs No	**−2.971**	**−4.339**	**−1.602**	−1.847	−4.773	1.079	**−3.500**	**−5.966**	**−1.034**	**−4.101**	**−7.180**	**−1.022**	−2.185	−4.748	0.378
Yes, severe vs No	−2.300	−6.351	1.751	4.292	−1.133	9.718	2.876	−4.191	9.942	−3.098	−11.701	5.506	−6.481	−13.226	0.264
Knowing people who had COVID-19															
Yes, alive vs No	0.334	−0.551	1.219	−0.022	−1.739	1.695	0.457	−1.229	2.142	0.307	−1.507	2.122	−0.031	−1.869	1.806
Yes, deceased vs No	**2.281**	**1.449**	**3.113**	**1.690**	**0.048**	**3.331**	**2.588**	**1.018**	**4.159**	**2.137**	**0.464**	**3.811**	**2.632**	**0.854**	**4.409**
Wave															
Wave 2 vs Wave 1	0.367	−0.499	1.233												
Wave 3 vs Wave 1	−0.078	−0.964	0.809												
Wave 4 vs Wave 1	−0.416	−1.341	0.509												
Constant	77.429	75.394	79.463	79.467	75.590	83.343	75.854	72.253	79.455	76.309	72.328	80.290	77.991	73.612	82.371

[a] Unstandardised coefficients.

deceased from the infection were associated with higher levels of COVID-19 protective behaviour. This result confirms previous reports showing that conspiracy mentality is inversely associated with adherence to medication regimens, preventive action and willingness to vaccinate.[9–13] This association may be because individuals with generic conspirative mentality (i.e. not strictly related to the pandemic) were probably more likely to adhere to conspirative theories about the real existence and extension of the COVID-19 pandemic (e.g. believing that the pandemic was exacerbated by media or institutions). This may explain why they were more likely to not comply with protective behaviours.

Limitations

This study has several limitations. Because we used an online survey, it is likely that the findings of the study underrepresented the responses of those with certain demographic characteristics (e.g. less educated and less affluent people and older respondents). Not everybody has access to the Internet; the online survey methodology is relatively uncontrolled, and the results are less generalisable. Furthermore, the Conspiracy Mentality Questionnaire assesses generic beliefs in conspiracy theories and is not specifically related to the COVID-19 pandemic. Finally, R2 for all models are quite low, and this implies that factors other than sociodemographics, not included in the models, might help explain the variability of conspiracy and protective behaviours.

Conclusions

This study highlights that individuals aged >35 years, poorly educated and particularly worried about their financial situations are at a particular risk of reporting higher levels of conspiracy mentality. Conspiracy mentality in Italy during the COVID-19 pandemic was medium–high and increased slightly over time, in parallel with a decrease in trust in health institutions and scientific/formal informational sources. Furthermore, conspirative mentality was a risk factor for low levels of COVID-19 protective behaviours.

Our findings highlight that during a pandemic, there is an urgent need for clear, effective and earnest communication tailored to specific population subgroups that for their sociodemographic characteristics might be more vulnerable to conspirative mentality. This may improve trust in health institutions and official information sources and, in turn, increase compliance with protective behaviour recommended by public health authorities.

Author statements

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Ethical approval

The studies involving human participants were reviewed and approved by IRCCS San John of God Fatebenefratelli of Brescia (protocol 286/2020). The patients/participants provided their written informed consent to participate in this study.

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Competing interests

None declared.

Data availability

The data sets presented in this study can be found in online repositories. Data sets and codes are available here: http://doi.org/10.5281/zenodo.5040719.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.11.005.

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Original Research

COVID-19 pandemic in prisons in Spain: characteristics of cases and implemented control measures, March 2020–June 2022

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ABSTRACT

Objectives: Our aim was to describe the epidemiological characteristics of COVID-19 cases in prison inmates in Spain and the control measures implemented to response to this public health challenge.
Study design: Retrospective observational study.
Methods: All COVID-19–confirmed cases reported to the Spanish information system in prisons between March 2020 and June 2022 were analyzed. Prevention plans and protocols established by penitentiary and health authorities were reviewed. Likewise, information on vaccines administered to prison inmates was described.
Results: A total of 8500 COVID-19 cases were reported to penitentiary public health surveillance. The overall cumulative incidence (CI) was 2054.18 cases per 10,000 inmate population. By epidemic periods, the average weekly CI was 1.15 per 10,000 inmate population during the first period, 6.91 during the second, 25.18 during the third, 3.53 during the fourth, 23.27 during the fifth, 34.72 during the sixth and 25.68 during the seventh period. The median age of cases was 49.2 years, 69.1% was born in Spain, 64.1% was asymptomatic and 16 cases died. Ninety-four percent were vaccinated. Control measures such as lockdown, suspending visitation rights and confining inmates in their cells were adopted at the beginning of the pandemic. These measures changed in accordance with the COVID-19 situation in the general population with a view to restoring the inmates' rights.
Conclusion: The COVID-19 pandemic has had a moderate incidence in Spanish prisons. Hospitalization and CFR were lower than the general population. The control measures adopted against COVID-19 have contributed to preventing and controlling the number of cases in prisons.

Introduction

More than 10 million people are incarcerated worldwide.[1] Infectious diseases spread easily and quickly in closed institutions such as prisons, and outbreaks can lead to serious consequences. This results in prisoners being at higher risk for infectious diseases than outside communities. Highly infectious prison environments are characterized by overcrowding with unavoidable close contact and poor ventilation.[2] Furthermore, prisons have their own health services, and the prevalence of high-risk behaviors among prison populations is higher than in the general population. The outbreak of COVID-19 in prisons has emphasized the need to implement prison-specific healthcare control measures.[3]

The first response from most European countries to the COVID-19 pandemic was to replicate the community measures, such as placing prisons in lockdown. To reduce overcrowding and cut the prison population, some countries reported that prisoners were released under judicial review between January and April.[4] Furthermore, in April 2020, the European Committee for the Prevention of Torture (CPT) urged the implementation of alternatives to detention wherever possible.[5]

In Spain, around 42,000 people were incarcerated during 2020–2021 in 71 penitentiary centers. Our main objective was to describe the epidemiological characteristics of COVID-19 cases in

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Spanish prisons and the control measures implemented to respond to the public health challenge.

Methods

Study design and population

A retrospective study was performed between March 1, 2020, and June 30, 2022, in Spanish prisons, excluding those in Catalonia (all the study period) and, those in Basque Country (since October 1, 2021), whose competencies were decentralized. All COVID-19–confirmed cases among prisoners in Grades 1 and 2 were included. Most prisoners are placed by default in Grade 2, and they are allowed to share common areas and participate in educational or work activities. Prisoners considered dangerous are placed in Grade 1, which implies restrictions in terms of communication and other privileges. Grade 3 prisoners (semi-freedom) were not included in this analysis because their health care depends on regional healthcare systems, rather than on the prisons' healthcare services.

Source of information and variables

Epidemiological information was gathered by the penitentiary public health surveillance system. Sociodemographic and clinical information was collected by prison physicians as part of the standard surveillance system. The variables collected were the following: demographic variables (sex, age, birth region), clinical presentation (asymptomatic – those who were identified by screening or contact tracing showing no symptoms and who did not develop any throughout the course of infection; mild symptoms – defined as those who presented some symptoms; and severe symptoms – defined as those who needed hospitalization) and infection severity (hospitalization, intensive care unit (ICU) admission, exitus), date and penitentiary center of diagnosis.

We reviewed nationwide and regional prevention plans and protocols established by the authorities of the Ministries of Health and Home Affairs. Measures such as physical distancing (limited outside contacts, restricted access to non-essential staff, activities suspension, prisoners exchange), preventive measures (testing algorithms, access to and use of personal protection equipment, hygiene practices, voluntary isolation in cells, adaptation of schedules), ventilation, cleaning and disinfesting strategies were summarized.

Among the control measures analyzed, information about vaccination schedule (type of vaccine and dose) was also collected and reviewed.

Data analysis

An epidemic curve was plotted with the number of confirmed cases by date of diagnosis as well as drawing a comparison with the epidemic period in the general population in Spain (data published by Institute of Health Carlos III – https://cnecovid.isciii.es/).

A descriptive analysis, overall and by age groups, was carried out using frequency tables for categorical variables and median and interquartile range (IQR) for continuous ones. The χ^2 test for independence was used to compare categorical variables and the non-parametric Mann–Whitney test to compare continuous variables.

Crude case fatality rate (CFR) was calculated as the total number of COVID-19 deaths divided by the total number of diagnosed cases.

The percentages of hospitalized cases and CFR in the inmate population were compared with the general population in Spain (data published by Institute of Health Carlos III - https://cnecovid.isciii.es/covid19). (Note: Since March 28, 2022, the national surveillance and control strategy changed and only cases aged 60 years and older were reported.)

All the statistical analyses were performed using Stata software (version 16.0; Stata Corporation, College Station, TX, USA).

Results

Evolution of COVID-19 pandemic

Between March 12, 2020 (the first COVID-19 case in a Spanish prison), and June 30, 2022, 8500 COVID-19 prison cases were reported to the prison monitoring system. The evolution of the COVID-19 pandemic in the Spanish prison population is shown in Fig. 1.

Based on our data, seven different periods by COVID-19 number of cases per epidemiologic week can be described: *Period 1:* From the pandemic declaration to July 3, 2020, when the end of the state of emergency is announced; *Period 2:* From July 4 to December 31, 2020, when the cumulative incidence (CI) of confirmed cases shows the connection point between the second and third epidemic periods; *Period 3*: From January 1 to March 31, 2021, the CI of confirmed cases shows the connection point between the third and fourth epidemic periods; *Period 4:* From April 1 to June 30, 2021, the CI of confirmed cases shows the connection point between the fourth and fifth epidemic periods; *Period 5:* From July 1 to September 30, 2021, the CI of confirmed cases shows the connection point between the fifth and sixth epidemic periods; *Period 6:* From October 1 to March 28, 2022, when the COVID-19 national surveillance and control strategy changed and *Period 7*: From March 29 to data extraction date (June 30, 2022).

The first period accumulated 1.0% of the total cases; the second period accounted for 8.6%; the third for 13.8%; the fourth for 2.2%; the fifth for 14.7%; the sixth for 43.0% and the seventh period for 16.6%.

Cumulative incidence

The overall CI was 2054.18 cases per 10,000 inmate population in the study period. By epidemic periods, the average weekly CI was 1.15 per 10,000 inmate population during the first period, 6.91 during the second period, 25.18 during the third, 3.53 during the fourth, 23.27 during the fifth, 34.72 during the sixth and 25.68 during the seventh period.

The distribution of CI varied according to autonomous regions and epidemic periods. Globally, Aragón showed the highest CI (3163.00 cases per 10,000 inmate population) followed by La Rioja (2983.87), Valencia (2907.71), Castilla y Leon (2631.91) and Madrid (2591.56). During the first wave, Madrid showed the highest CI (118.25 per 10,000 inmate population), Castilla y León (630.04 per 10,000 inmate population) during the second wave, Aragon (1002.59 per 10,000 inmate population) during the third wave, Canary Islands (164.58 per 10,000 inmate population) during the fourth wave, La Rioja (1859.16 per 10,000 inmate population) during the fifth wave, Murcia (1092.38 per 10,000 inmate population) during the sixth wave and Extremadura (818.18 per 10,000 inmate population) during the seventh wave (Fig. 2).

As opposed to the COVID-19 14-day CI in the general population in Spain, we observed a delay of two weeks in the CI in penitentiaries over the study period, although for the sixth period, the CI in prisons began to increase before that of the general population. The maximum value of 14-day CI in the general population was higher (first, second and sixth periods) than or similar (third and fourth) to

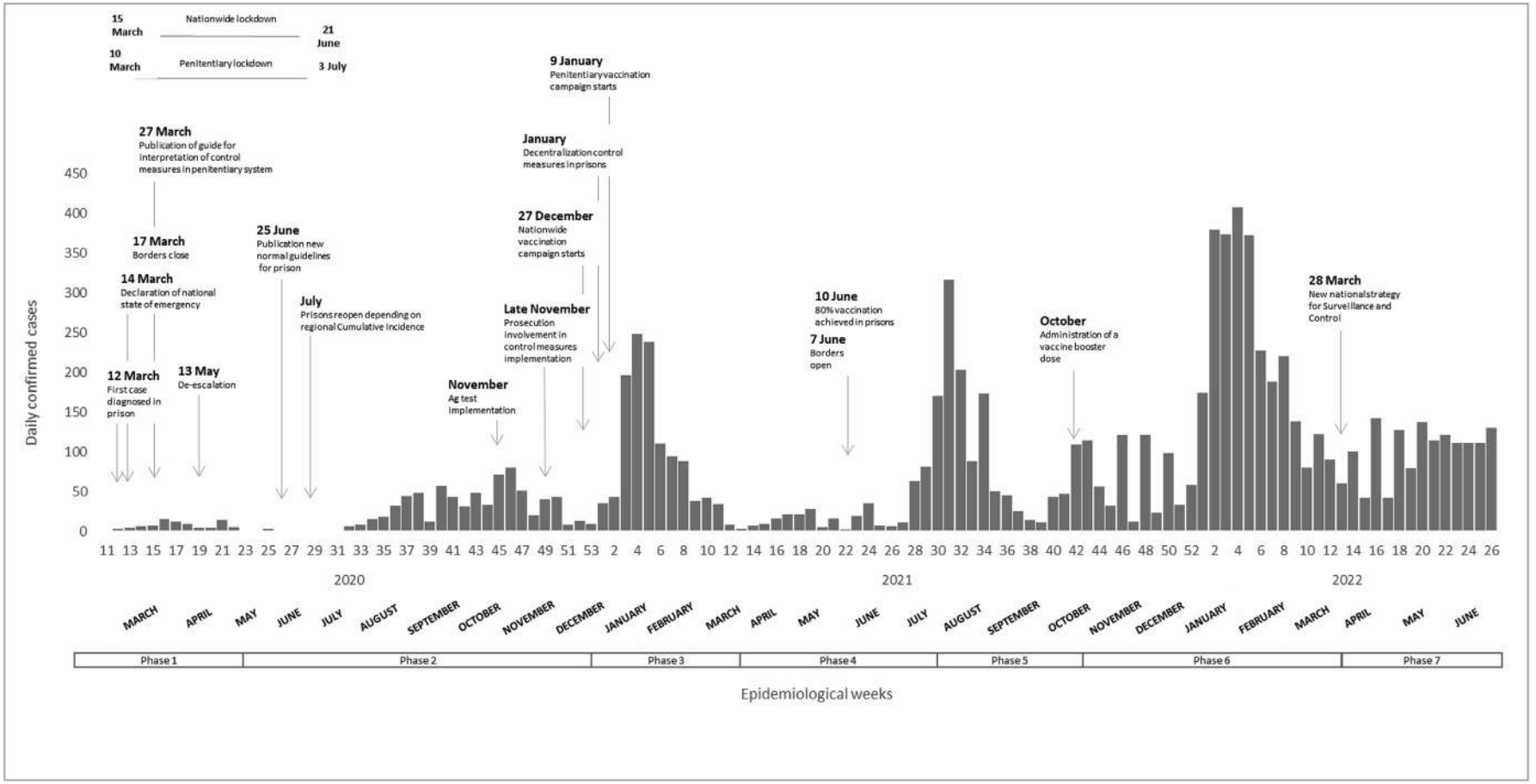

Fig. 1. Number of confirmed COVID-19 cases, national implemented control measures and announcements in prisons.

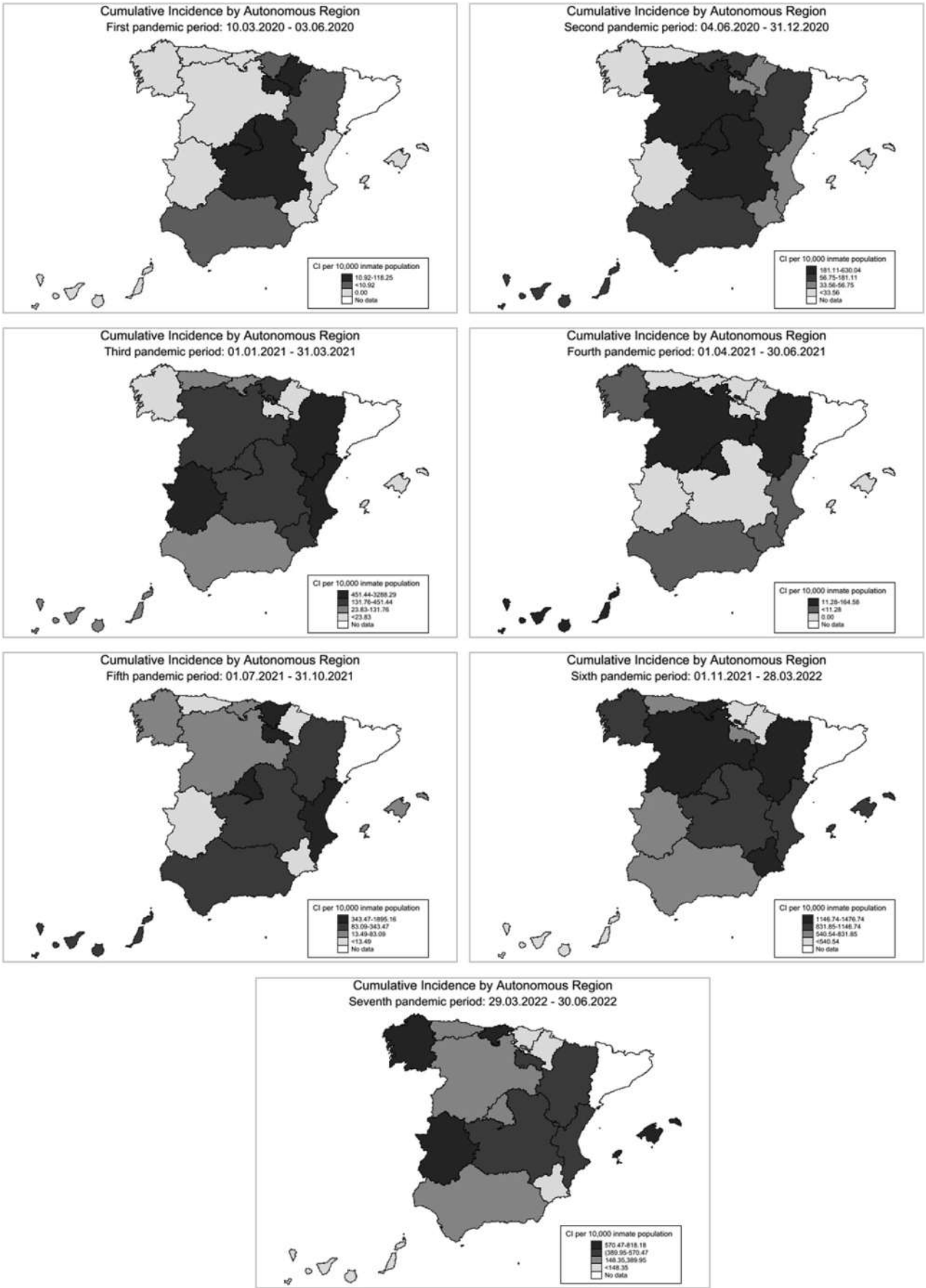

Fig. 2. Cumulative incidence of COVID-19 cases in penitentiary institutions by inmate population and autonomous regions and pandemic periods, Spain, March 2020–June 2022.

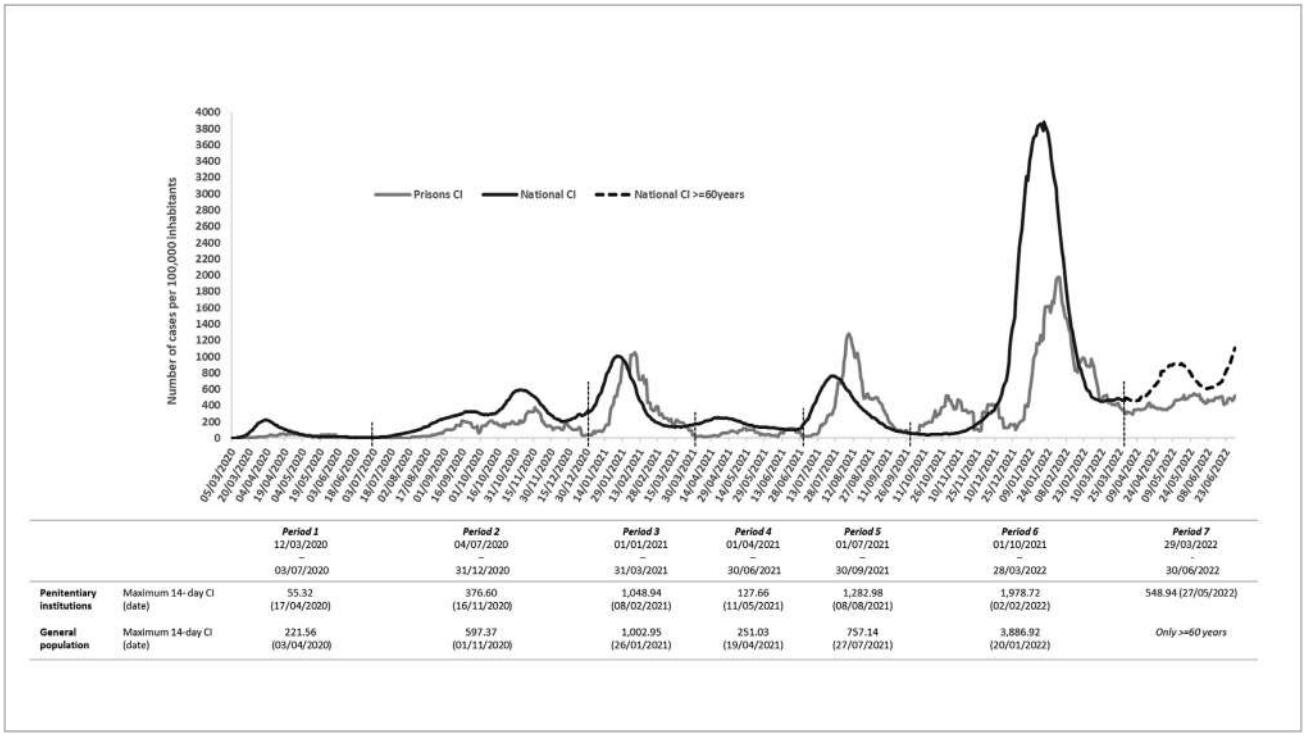

Fig. 3. COVID-19 14-day cumulative incidence in penitentiaries and in the general population.

Table 1
Demographic and clinical characteristics of COVID-19 cases in prisons, Spain, March 2020–June 2022.

	Total		Age group (years)								***P*-value**
			18–29		30–39		40–49		≥50		
	N	%	N	%	N	%	N	%	N	%	
Total	8500	100	1503	17.7	2549	30.0	2392	28.1	2506	24.2	
Sex											0.431
Men	8006	94.2	1414	94.1	2415	94.7	2240	93.6	1937	94.2	
Women	494	5.8	89	5.9	134	5.3	152	6.4	119	5.8	
Region of birth											**<0.001**
Spain	5877	69.1	821	54.6	1667	65.4	1756	73.4	1633	79.4	
Latin America	827	9.7	192	12.8	279	10.9	215	9.0	141	6.9	
Europe	765	9.0	139	9.2	253	9.9	207	8.6	166	8.1	
North Africa & Middle East	747	8.8	295	19.6	253	9.9	125	5.2	74	3.6	
Sub Saharan Africa	210	2.5	42	2.8	77	3.0	65	2.7	26	1.3	
Asia & Pacific	64	0.8	10	0.7	17	0.7	23	1.0	14	0.7	
Unknown	10	0.1	4	0.3	3	0.1	1	0.04	2	0.1	
Clinical presentation											**<0.001**
Asymptomatic	5451	64.1	1049	69.8	1653	64.8	1515	63.3	1234	60.0	
Mild symptoms	2912	34.3	452	30.1	885	34.7	851	35.6	724	35.2	
Severe symptoms	137	1.6	2	0.1	11	0.4	26	1.1	98	4.8	
Hospitalization – Yes	137	1.6	2	0.1	11	0.4	26	1.1	98	4.8	**<0.001**
Death	16	0.2	0	0	0	0	2	0.1	14	0.7	**<0.001**

Table 2
Hospitalization and CFR rate among the COVID-19 cases in penitentiary institutions and the general population[a] according to pandemic period.

	Penitentiary institutions		General population	
	Hospitalization rate	CFR	Hospitalization rate	CFR
Period 1 (12/03/2020–03/07/2020)	20.2%	2.38%	44.1%	11.8%
Period 2 (04/07/2020–31/12/2020)	4.1%	0.14%	7.4%	1.5%
Period 3 (01/01/2021–31/033/2021)	2.6%	0.59%	7.7%	1.8%
Period 4 (01/04/2021–31/03/2021)	3.7%	0%	7.2%	0.8%
Period 5 (01/07/2021–30/09/2021)	2.5%	0.08%	3.8%	0.5%
Period 6[a] (29/03/2022–30/06/2022)	0.5%	0.14%	1.5%[a]	0.2%[a]

[a] Data available for the general population until 28/03/2022.

that of penitentiaries in all epidemic periods, with the exception of the fifth one, where the peak of 14-day CI in penitentiaries was 1282.98 versus 742.70 in the general population. In the sixth period, the 14-day CI in the general population reached a value of 3886.92 in January 21, 2022, while the maximum CI value in the prisoners was 1978.72 in February 2, 2022 (Fig. 3).

Table 1 shows the main characteristics of the 8500 COVID-19 prison cases. The median age of COVID-19 cases was 49.2 years (IQR: 32.2–49.2 years), similar in males and females, and 24.2% of cases were older than 50 years. Women accounted for 5.8% of the total number of cases.

69.2% of cases were born in Spain, followed by 9.7% from Latin-American countries, 9.0% from Europe and 8.8% from North Africa and Middle East. The median age of Spanish cases was 41.9 years (IQR: 33.9–50.5 years), whereas it was 36.4 years for foreign cases (IQR: 29.2–44.9 years) ($P < 0.001$).

Most cases, 64.1% (5451 cases) were asymptomatic, identified by screening or contact tracing, 34.3% (2912 cases) presented mild symptoms, and 1.6% showed severe symptoms that required hospitalization ($P < 0.001$). By sex, 64.6% of men were asymptomatic versus 56.9% of women ($P = 0.001$), 33.8% of men presented mild symptoms compared to 41.7% of women ($P < 0.001$) and 1.6% of men and 1.4% of women presented severe symptoms ($P < 0.723$).

The presence of severe symptoms was more likely among patients older than 50 years (4.8%) than younger (0.1%, 18–29 years; 0.4%, 30–39 years and 1.1%, 40–49 years; $P < 0.001$). Among all cases, 1.6% (137 cases) were hospitalized. The percentage of patients hospitalized increased with age; 71.5% of the hospitalizations occurred among cases aged 50 years and older. The highest percentage of hospitalizations occurred during the first period (20.2%) and the lowest in the sixth (0.5%), as in the general population (Table 2).

Sixteen cases died (CFR: 0.19%), their median age being 61.5 years (IQR: 51.6–76.3 years). Seven deaths (43.7%) (CFR: 0.59%) were during the third period, five deaths (31.2%) (CFR: 0.08%) happened during the sixth period, two deaths (12.5%) (CFR: 2.38%) during the first period, and one death (6.2%) (CFR: 0.14%) during second and (CFR: 0.08%) fifth period, respectively. All deaths were from COVID-19, except four people who died of other causes.

Control measures

The main national events and public health measures are shown in Fig. 1. The initial response was to emulate the community's response to COVID-19: placing prisons in lockdown, suspending visitation rights and confining inmates to very little movement outside their cells. As visitation was suspended, free telephone and videoconferencing with families and attorneys were implemented.

On January 31, 2020, the General Secretariat of Penitentiaries sent an action algorithm for prisons, included as part of the first General Protocol of Action. This algorithm provided contact tracing guidance. First control measures for prisons were issued on March 5, 2020, after the first cases were reported in Spain (February 26). Prisons in four provinces were the first penitentiaries in lockdown due to community transmission being detected. On March 10, 2020, the rest of Spanish prisons were closed. On March 12, the state of emergency was declared.[6] The Ministries of Health and Home Affairs (the General Secretariat of Penitentiaries) published a technical report on March 27, 2020. In this document, the following main measures were established: collection of samples and their transport to the laboratory, isolation and transfer of probable and confirmed cases, contact tracing, judicial proceeding of cases under investigation.

Furthermore, new prison admission was placed in quarantine to prevent transmission from asymptomatic cases. At the end of the quarantine period, a screening test was performed.

First de-escalation measures were announced by the General Secretariat of Penitentiaries to prisons on May 13, including health measures. On June 10, an updated and consolidated version was published by the Ministries of Health and Home Affairs.

For the second COVID-19 period, a dynamic control strategy was implemented in phases according to regional CI: a) Phase I, when CI was lower than 250, open visits (vis a vis) and family visits were cancelled; b) Phase II, (CI > 250), in-person visiting at 50% capacity and suspension of exit permits and c) Phase III (CI > 500), full lockdown of the center.

On June 25, the General Secretariat of Penitentiaries published a 'new normal' measure report related to: resumption of prison activities, inmate transfers, exits, appointments with relatives, resumption of face-to-face visits for inmates who were on probation by a judicial authority, as long as their health and the pandemic situation allowed for it.[7]

To face the third COVID-19 period in prison, the Spanish Prosecutor's Office began to review the restrictions in place to align them with the measures proposed by public health institutions as of late November 2020.[8]

Quarantine of close contacts (residents in the same module as the case) was established in the form of cell isolation for 10 days, if they were not vaccinated or fully vaccinated, and in the form of restricted movement within their module and in 'bubble' groups in the courtyard, if they were vaccinated. For new admissions to prison and furloughs, a cell quarantine was maintained for 7 days for people who were fully vaccinated and for 10 days if they had not been vaccinated. In the context of community transmission, limited contact between prison and the outside world was recommended.

The COVID-19 vaccination campaign started on January 9, 2021, in penitentiaries (vaccination in the general population started on December 27, 2020). The inmate population was considered a vulnerable population, as they are in closed environments with a higher risk of exposure to the disease and infection. At that time, there were four vaccines approved for use in Spain: BioNTech-Pfizer (Cominarty, BNT162b2), Moderna (Spikevax, mRNA-1273), Janssen (Ad26. COV2-s (recombinant)) and Oxford-AstraZeneca (Vaxzevria, ChAdOx1/nCoV-19). In the first months of the prison vaccination campaign, health authorities prioritized the Janssen vaccine over other types/brands because it required only one dose. In the following months, the other brands were used interchangeably.

Since October 2021, a booster dose was administrated in penitentiaries. The vaccination status of prisoners was assessed on admission to prison and they were vaccinated if necessary, according to national recommendations for the general population.

By June 30, 2022, 94.0% inmates were fully vaccinated, 3.1% were still pending to completion of the vaccine series and 2.9% inmates refused vaccination. Regarding the vaccines type/brand, 31.7% of inmates received the Janssen Covid-19 vaccine, 33.7% Pfizer-BioNTech's, 29.5% Moderna's, 2.9% others. Among fully vaccinated inmates, the Janssen Covid-19 vaccine was the more frequently used (65.8%) as a first dose, followed by Pfizer-BioNTech's (18.7%) and Moderna's (10.0%). As a booster dose, 53.5% received the Moderna Covid-19 vaccine and 44.9% Pfizer-BioNtech's.

The median age of inmates vaccinated was 41 years (IQR: 33–49 years), whereas the median age of those refusing vaccination was 36 years (IQR: 28–45 years) ($P < 0.001$). Three percent of men refused vaccination compared to 1.7% of women ($P < 0.001$).

Discussion

To our knowledge, this is the first study that describes the epidemiology of the COVID-19 pandemic in Spanish prisons and the implementation of public health measures. Our results show a moderate incidence of coronavirus disease in prisons.

Hospitalization and CFR were lower than the general population, although they are not fully comparable populations.

Most COVID-19 cases were asymptomatic, only 1.6% of the total were hospitalized and the CFR was 0.19% during the study period. Data published from a COVID-19 outbreak observed in a Catalonian prison also reported that 95% of cases were asymptomatic.[9] The presence of severe symptoms, hospitalization and death were more frequent among older people, as was the case with the general population.[10]

Since the COVID-19 pandemic was declared, 8500 cases have been reported to the public health Central Prison Monitoring System over a period of 28 months, from March 1, 2020, to June 30, 2022. The early nationwide lockdown implemented in penitentiaries on March 10 led to a first flat epidemic curve. The number of cases began to increase as of September 2020, when the second pandemic period started. During this period, there were movement restrictions both in the general population and penitentiaries, which were correlated with a decrease in CI at the end of 2020. The third pandemic period began in prisons at the end of January 2021, approximately two weeks later than in the general population. During that period, the CI in prisons was similar to the CI observed in the general population, unlike what occurred in the previous two. In February 2021, control measures in prison were decentralized. From that moment on, the recommendations and measures adopted were based on the CI of the province where the prison was located, together with the prisons' inspection judges and the bodies responsible for public health in each autonomous region. The fourth pandemic period was milder than the previous ones, probably due to the large number of cases that occurred in the immediately preceding period and the vaccination program that started in prisons at the beginning of January 2021. As in previous periods, in the fifth pandemic period, the increase in prison cases was observed two weeks after the increase in the general population. During this period, the maximum 14-day CI peak observed in prisons exceeded that reached in the general population (1282.98 vs 742.70 per 100,000 inhabitants, respectively). The beginning of the sixth pandemic period came early in the prison compared to the general population, but 14-day CI in the general population was higher than inmate population (3886.92 vs 1978.72 per 100,000 inhabitants, respectively).

The higher number of cases observed in the fifth and sixth pandemic periods in the inmate population could be due to some extent to the vaccination campaign conducted in prisons. Most inmates were vaccinated with Janssen, following the recommendation approved by the Ministry of Health's Interterritorial Board. This vaccine only required one dose, which made it easier to complete vaccination in this fast-changing population (entry-exit in prison) that has a high degree of mobility. However, several subsequent studies have shown that loss of immunity occurs faster in people vaccinated with Janssen, as opposed to those vaccinated with Moderna or Pfizer.[11–13] According to data published by the Spanish Ministry of Health, Janssen's vaccine showed a much lower efficacy against infection and symptomatic infection, while the protection against hospitalization and death was somewhat lower for Janssen's vaccine than others (Pfizer, Moderna and AstraZeneca).[14] Furthermore, the large increase observed in the sixth period was due to the emergence of the new Omicron variant of SARS-CoV2, which had higher transmissibility but lower symptomatology and risk of hospitalization.[15,16]

The moderate incidence of COVID-19 cases shown in our study contrasts with the deficiencies of the prison systems worldwide, e.g., overcrowding in prison settings, lack of resources and health and social support in the prison health-care services,[17–19] which have posed additional challenges to mitigate the effects of this disease in the prison population. In Spanish prisons, as in most European countries,[4,20,21] the control measures implemented against COVID-19 emulated the community's response: prison lockdown, suspending visitation rights and limiting movement outside the cells. In our context, the collaboration between the health care and public health services in the regions where the prisons are located has made it possible to provide a level of care to the prison population comparable to that of the general population in the face of the COVID-19 pandemic. Furthermore, the measures established during the pandemic were well accepted by inmates, despite their rights being restricted in terms of communication, permits and others. In this regard, the intervention of health and management teams and the information on health education provided to inmate by all workers played an essential role. On-demand consultations, group workshops and other types of meeting were organized to inform inmates about the benefits of hygiene measures (handwashing, use of mask, social distancing, …) and restrictive measures (restriction of communication with relatives, open visits, exit permits, quarantine and isolation) in order to control the epidemic.

In conclusion, although prisons are closed settings that could amplify and spread infectious diseases both inside and outside their walls, measures established in Spanish prisons have made it possible to contain the spread of the COVID-19 epidemic.

Author statements

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Ethics approval

The study was performed in accordance with the requirements of the Spanish legislation on data protection. Ethical approval was not sought since data were collected by routine surveillance systems. No personal identifiers were collected in this study; only aggregated anonymized data were used. Informed consent for epidemiological surveillance is deemed unnecessary according to national regulations (Act 33/2011, of October 4, General Public Health, BOE-A-2011-15623. Section 41 and Constitutional Act 3/2018, of December 5, on the protection of Personal Data and Guarantee of Digital Rights. Additional provision 17).

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Competing interests

The authors declare no competing interests.

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Original Research

COVID-19 vaccines effectiveness against symptomatic disease and severe outcomes, 2021–2022: a test-negative case–control study

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ABSTRACT

Objectives: This study evaluated the effectiveness of COVID-19 vaccines in preventing symptomatic and severe disease.
Study design: This was an observational test-negative case–control study.
Methods: Study participants were adults with at least one symptom included in the World Health Organization COVID-19 definition who sought health care in a public emergency department between 1 November 2021 and 2 March 2022 (corresponding with the fifth pandemic wave in Portugal dominated by the Omicron variant). This study used multivariable logistic regression models to estimate and compare the odds ratio of vaccination between test-positive cases and test-negative controls to calculate the absolute and relative vaccine effectiveness.
Results: The study included 1059 individuals (522 cases and 537 controls) with a median age of 56 years and 58% were women. Compared with the effectiveness of the primary vaccination scheme that had been completed ≥180 days earlier, the relative effectiveness against symptomatic infection of a booster administered between 14 and 132 days earlier was 71% (95% confidence interval [CI]: 57%, 81%; $P < 0.001$). The effectiveness of the primary series against symptomatic infection peaked at 85% (95% CI: 56%, 95%) between 14 and 90 days after the last inoculation and decreased to 34% (95% CI: −43%, 50%) after ≥180 days.
Conclusions: Despite the known immunological evasion characteristics of the Omicron variant, results from this study show that vaccine effectiveness increases after booster administration. COVID-19 vaccine effectiveness decreases to less than 50% between 3 and 6 months after completion of the primary cycle; therefore, this would be an appropriate time to administer a booster to restore immunity.

Introduction

Real-world studies have revealed that COVID-19 vaccines offer excellent short-term protection against human SARS-CoV-2 infection and its severe consequences, including hospitalisation and death.[1,2] In addition, vaccination and non-pharmacological measures have resulted in fewer people requiring hospitalisation, despite the latest high-incidence waves.[3] However, recently, concerns have been raised regarding the reduced effectiveness of the vaccines against new variants of concern.[4] Moreover, there is evidence that protection against symptomatic disease wanes over time.[5,6]

Results regarding booster protection against severe COVID-19 due to the Omicron variant are inconsistent. Some studies have

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suggested robust protection similar to the effectiveness against prior variants,[7,8] while other studies have reported reduced protection against the Omicron variant and further reduction over time after the booster dose.[9–11]

The vaccination campaign in Portugal started on 27 December 2020 with the Comirnaty vaccine developed by Pfizer-BioNTech, Mainz, Germany/New York, USA, followed by Spikevax from Moderna, Cambridge, USA, in the first weeks of January 2021, Vaxzevria from AstraZeneca, Cambridge, UK, on 7 February 2021 and Jcovden from Janssen, Beerse, Belgium, on 14 April 2021. Thus, these were the four vaccines approved for use in the EU/EEA during the data collection period.

This test-negative case–control study aims to evaluate the effectiveness of COVID-19 vaccines in preventing symptomatic and severe disease in Alto Minho, Portugal, during the fifth pandemic wave.[12]

Methods

Participants

Study participants were individuals aged ≥18 years who were residents of Alto Minho, had at least one symptom included in the World Health Organization (WHO) COVID-19 definition,[13] sought health care in a public emergency department in the region between 1 November 2021 and 2 March 2022, and were tested for SARS-CoV-2 using respiratory samples. Alto Minho is a Nomenclature of Territorial Units (NUTS) III region with 231,293 inhabitants according to the 2021 census[12] and is located in the Northern region of Portugal. This region was one of the most affected regions in Portugal and where the first cases of COVID-19 arose. A local approach was used for this study to enable access to more detailed and complete data.

Exclusion criteria included individuals who were not eligible for vaccination against COVID-19, those with unavailable laboratory test results, those without information on vaccination status and those with a symptom onset of more than 10 days before the test date. In addition, all individuals who had previously tested positive for COVID-19 were excluded from the analysis to minimise bias caused by natural immunity.

Study design

In this test-negative case–control study, the effectiveness of COVID-19 vaccines against symptomatic and severe SARS-CoV-2 infection was estimated, as described in detail elsewhere.[14] In brief, study participants were divided into two groups: SARS-CoV-2 test-positive cases and test-negative controls. Vaccination status between participants with symptomatic COVID-19 and those with reported symptoms but with a negative test result were compared. In addition, vaccination status between the patients with moderate-to-severe COVID-19 and those with mild COVID-19 were also compared.

Outcomes

The following were considered as the primary outcomes:

(1) Symptomatic SARS-CoV-2 infection confirmed with rRT-PCR tests, antigen tests or Xpress RT-PCR tests performed on respiratory samples from the nasopharynx or oropharynx; and
(2) Moderate-to-severe disease associated with SARS-CoV-2 infection defined by hospitalisation over 24 h, intermediate or intensive care unit (I/ICU) admission or death with a recent positive test result.

Hypothesis

The hypothesis questions tested were as follows:

(1) Is the effectiveness of COVID-19 vaccines against symptomatic disease due to the Omicron variant higher than 50%?; and
(2) Does the effectiveness of COVID-19 vaccines wane over time?

Sample size

According to the WHO guidelines,[15] the minimum sample size (N_1) in a test-negative case–control study should be calculated using the following formula:

$$N_1 = (z/d)^2[1/A(1-A)+1/CP_2(1-P_2)]$$

where C is the control-to-case ratio; P_2 is the prevalence of vaccine exposure in the control group (i.e. vaccine coverage in the population being studied); $A = P_2(1-VE)/[1-P_2(VE)]$, where VE denotes the anticipated effectiveness of the vaccine; z denotes the (1-α) percentage point of the standardised normal distribution (normally, this is based on an α-value of 0.05 and thus a z-value of 1.96); and d is determined by solving the equation $W(\widehat{\beta},\widehat{d}) = \exp(\widehat{\beta})(\exp(\widehat{d}) - (\exp(-\widehat{d}))$ where $\widehat{d} = z\widehat{\sigma}$ and where and $W(\widehat{\beta},\widehat{d})$ denotes the confidence interval width. The number of controls needed is then calculated as $C*N_1$.[15]

Therefore, assuming a vaccine coverage of 90%, as the vaccine coverage for primary series vaccination was 88% in mainland Portugal in the middle of the study period, this study needed a sample size of at least 580 cases and 580 controls to detect an anticipated vaccine effectiveness (VE) of 70%, with a precision estimate of ±10%, and a type 1 error probability of 0.05.

Data sources

Databases extracted from Clinidata were used to identify all SARS-CoV-2 tests performed in the public emergency departments in Alto Minho during the study period. Participants' vaccination status were obtained from the national vaccination registry, including the type of vaccine, number of doses and date of inoculation. These and other clinical and sociodemographic variables were complemented with data from patients' electronic medical records and from the national platform of contact tracing (Trace COVID-19).

Covariates

Health and demographic data were collected, including age, sex, municipality of residence and comorbidities that confer an extremely vulnerable status,[16] including the following: (1) solid organ transplant receptors under long-term immunosuppression; (2) patients with active cancer under chemotherapy/radiotherapy or radical radiotherapy for lung cancer; (3) individuals under immunotherapy or other continuous antibody treatments for cancer; (4) patients under other directed cancer treatments that affect the immunological system, such as kinase protein or poly (ADP-ribose) polymerase inhibitors; (5) patients with haematologic cancer with leukaemia, lymphoma or myeloma in any treatment stage; (6) patients who have undergone bone marrow transplant or

stem cell treatment in the last 6 months or who are currently under immunosuppressive treatment; (7) patients with severe respiratory disease, including severe asthma and severe chronic obstructive pulmonary disease; (8) individuals with cystic fibrosis or idiopathic pulmonary fibrosis, regardless of disease stage; (9) patients with a rare disease and innate errors in metabolism that substantially increase the risk of infection (e.g. severe combined immunodeficiency and homozygotic sickle cell disease); (10) patients prescribed immunosuppressive therapy in the last 6 months; and (11) pregnant women with significant congenital heart disease.

The study sample included individuals who were (a) either unvaccinated or vaccinated with one dose less than 14 days before the symptom onset; (b) vaccinated with one dose of mRNA vaccine or Vaxzevria at least 14 days before the symptom onset or vaccinated with two doses of mRNA vaccine or Vaxzevria less than 14 days before the symptom onset (partially vaccinated); (c) vaccinated with two doses or one dose of Jcovden at least 14 days before the symptom onset (fully vaccinated) or vaccinated with a booster less than 14 days before the symptom onset; or (d) vaccinated with three doses or with Jcovden and a booster at least 14 days before the symptom onset.

Statistical analyses

In the univariate analysis, the Mann–Whitney test was used for continuous variables (age and time) and the chi-squared test or Fisher's exact test (every time there was a cell with under 10 observations) for categorical variables.

Multivariable logistic regression models were used to estimate and compare the odds ratios (ORs) of vaccination between the test-positive cases and test-negative controls; unvaccinated individuals were considered as a reference group for calculation of the absolute effectiveness and primary scheme completion between 14 and 179 days or ≥180 days earlier as a reference group for calculation of the relative effectiveness of a booster dose. The crude and adjusted ORs were estimated, accounting for all covariates, which were selected based on their known association with SARS-CoV-2 infection or severity and receipt of a COVID-19 vaccine,[16,17] and were assessed as potential confounders. VE was calculated using the following formula:

$$VE = (1-aOR) \times 100\%$$

Covariates were added to the model when they changed the OR by at least 5% or were statistically significant ($P < 0.05$). Thereafter, the main analysis was stratified by the type of vaccine (mRNA vs viral vector) and time from the last dose (14–179 or ≥180 days). This cut-off was selected according to the methodology used by Thompson et al.[11] and because 180 days is the recommended interval for inoculation with a booster after the primary series.[18]

The analysis was repeated for severe outcomes (hospitalisation over 24 h, I/ICU admission and/or death). Data analysis and graphical representation were conducted using the R software, Vienna, Austria (version 4.1.3 for Rstudio Build 461) with additional packages: 'readxl', 'xlsx', 'lubridate', 'dplyr', 'summarytools', 'car', 'splines', 'ggplot2', and 'ggpubr'.

The goodness of fit of the logistic regression models was assessed using the Hosmer–Lemeshow test instead of indicating a pseudo-R^2 as it does not have a clear interpretation.[19]

Possible interactions were evaluated between age and group of municipalities of residence in both models, and between age and extreme vulnerability status in the severe disease model. The likelihood ratio test was used to search for interactions.

This study included 1059 individuals (522 cases and 537 controls) with a median age of 56 years and 58% were women. Participant characteristics and eligibility criteria are shown in Table 1 and Fig. 1, respectively.

Results

Descriptive statistics and characteristics

The majority of study population were vaccinated with at least two doses of COVID-19 vaccine (89%), comparable to the national vaccine coverage during the study period.[15] In addition, most participants completed their primary scheme with mRNA vaccines, mainly Comirnaty (75%); among those administered with a booster, the last dose was an mRNA vaccine. Among the test-positive cases, 81 (16%) were hospitalised for more than 24 h; 12 (2%) were admitted to the I/ICU; and 18 (3%) died.

Effectiveness against symptomatic infection – crude model

The crude effectiveness of the primary vaccination scheme was 38% (95% confidence interval [CI]: 3%, 61%) between 14 and 179 days after the last vaccination, and 29% (95% CI: −17%, 57%) ≥180 days after the last vaccination (see Fig. 2A). The crude effectiveness of the primary scheme followed by a booster was 78% (95% CI: 65%, 86%).

Effectiveness against symptomatic infection – adjusted model

The absolute effectiveness of the primary vaccination series against symptomatic infection was lower ≥180 days after the last dose (34%; 95% CI: −12%, 61%) than between 14 and 179 days after the last dose (50%; 95% CI: 18%, 69%). Meanwhile, the absolute effectiveness of booster vaccination was higher (81%; 95% CI: 68%, 89%) than that of complete vaccination, as represented in Fig. 2A. The model was adjusted for age (as a continuous variable) using a cubic spline, for the group of municipalities of residence and the calendar month of testing, as shown in Table 2. Sex was not a confounder in any model in this study and extreme vulnerability status did not prove to be a confounder in this specific model.

Compared with the effectiveness of the primary vaccination scheme at 14–179 days after the last dose, the relative effectiveness of the booster vaccination was 63% (95% CI: 42%, 76%; $P < 0.001$). The relative effectiveness of booster vaccination was higher (71%; 95% CI: 57%, 81%; $P < 0.001$) than the effectiveness of the primary vaccination scheme ≥180 days after the last dose.

Type of vaccine

The effectiveness of the primary series against symptomatic infection was 56% (95% CI: 24%, 74%) and 41% (95% CI: −13%, 70%) between 14 and 179 days after the last dose of mRNA and viral vector vaccines, respectively. At ≥180 days after the last dose, the effectiveness of mRNA and viral vector vaccines was 40% (95% CI: −6%, 66%) and 33% (95% CI: −60%, 74%), respectively. The vaccine effectiveness stratified by the type of vaccine is presented in Fig. 2B.

The effectiveness of three doses of mRNA and viral vector vaccines and a booster dose with mRNA vaccine was 84% (95% CI: 70%, 92%) and 74% (95% CI: 30%, 90%), respectively. This model was adjusted for age (as a continuous variable) using a cubic spline, for the group of municipalities of residence and the calendar month of testing.

Table 1
Clinical and demographic characteristics of the study participants during the fifth pandemic wave dominated by the Omicron variant (1 November 2021 to 2 March 2022).

Characteristics	Total ($N = 1059$)	Cases ($n = 522$)	Controls ($n = 537$)	*P*-value
Age group in years [(n (%)]				
<65	622 (58.7%)	363 (69.5%)	259 (48.2%)	<0.001[a]
≥65	437 (41.3%)	159 (30.5%)	278 (51.8%)	
Age in years [median year (IQR)]	56 (37–78)	47 (33–71)	66 (44–81)	<0.001[a]
Sex [(n (%)]				
Male	441 (41.6%)	216 (41.4%)	225 (41.9%)	0.913
Female	618 (58.4%)	306 (58.6%)	312 (58.1%)	
Vaccination status [(n (%)]				
Unvaccinated	107 (10.1%)	72 (13.8%)	32 (6.5%)	<0.001[a]
Partially vaccinated	22 (2.1%)	14 (2.7%)	8 (1.5%)	
Fully vaccinated	563 (53.2%)	322 (61.7%)	241 (44.9%)	
Booster	367 (34.7%)	114 (45.4%)	253 (47.1%)	
Extremely vulnerable status [(n (%)]				
Yes	125 (11.8%)	54 (10.3%)	71 (13.2%)	0.175
No	934 (88.3%)	468 (89.7%)	466 (86.8%)	
Hospitalisation for >24 h [(n (%)]				
Yes	199 (18.8%)	81 (15.5%)	118 (22.0%)	0.009[a]
No	860 (81.2%)	441 (84.5%)	419 (78.0%)	
Test type [(n (%)]				
rRT-PCR	1042 (98.4%)	511 (97.9%)	531 (98.9%)	0.321
Xpress RT-PCR	4 (0.4%)	2 (0.4%)	2 (0.4%)	
Antigenic	13 (1.2%)	9 (1.7%)	4 (0.7%)	
Type of vaccine, if vaccinated [(n (%)]				
1st dose				
Comirnaty	633 (66.5%)	296 (65.8%)	337 (67.1%)	0.027[a]
Spikevax	129 (13.6%)	52 (11.6%)	77 (15.3%)	
Vaxzevria	106 (11.1%)	45 (10.0%)	61 (12.2%)	
Janssen	66 (6.9%)	41 (9.1%)	25 (5.0%)	
Missing	18 (1.9%)	16 (3.6%)	2 (0.4%)	
2nd dose				
Comirnaty	628 (72.0%)	290 (72.5%)	338 (71.6%)	
Spikevax	122 (14.0%)	49 (12.2%)	73 (15.5%)	
Vaxzevria	105 (12.0%)	45 (11.2%)	60 (12.7%)	0.428
Missing	17 (1.9%)	16 (4.0%)	1 (0.2%)	
3rd dose				
Comirnaty	344 (93.5%)	102 (88.7%)	242 (95.7%)	
Spikevax	21 (5.7%)	10 (8.7%)	11 (4.3%)	
Missing	3 (0.8%)	3 (2.6%)	0 (0%)	0.136
I/ICU admission [(n (%)]				
Yes	17 (1.6%)	12 (2.3%)	5 (0.9%)	0.127
No	1042 (98.4%)	510 (97.7%)	532 (99.1%)	
Residence [(n (%)]				
Vale do Minho	128 (12.1%)	39 (7.5%)	89 (16.6%)	<0.001[a]
Vale do Lima	931 (87.9%)	483 (92.5%)	448 (83.4%)	
Time between the date of the last dose and date of symptoms, if vaccinated [median no. of days (IQR)]				
Primary series	160 (134–195.5)	163.5 (138.3–196.8)	154 (123–193)	0.013[a]
Booster	57 (36.5–83)	62.5 (37.3–80.8)	56 (36–84)	0.576

The Mann–Whitney test was used for the continuous variables (age and time) and the chi-squared or Fisher's exact test for the categorical variables. IQR, interquartile range; I/ICU, intermediate or intensive care unit.
[a] Statistical significance for $\alpha = 0.05$.

Waning of effectiveness

Vaccine effectiveness decreased over time (Fig. 2C). The point estimate of the effectiveness of the primary series against symptomatic infection peaked at 85% (95% CI: 56%, 95%) between 14 and 90 days after the last inoculation and decreased to 66% (95% CI: 22%, 85%) between 91 and 120 days, 43% (95% CI: 2%, 67%) between 121 and 179 days, and 34% (95% CI: −30%, 56%) after ≥180 days (Fig. 2C).

The point estimate of the effectiveness of a booster was 83% (95% CI: 67%, 92%) between 14 and 42 days, remained stable (83%; 95% CI: 65%, 92%) between 43 and 70 days, and decreased after >70 days (69%; 95% CI: 23%, 88%). This model was adjusted for age (as a continuous variable) using a cubic spline, the group of municipalities of residence and the calendar month of testing.

Vaccine effectiveness for severe outcomes

The effectiveness of the primary vaccination series against severe outcomes was 83% (95% CI: 61%, 93%), while that with a booster was 90% (95% CI: 71%, 97%). Stratification showed an effectiveness of 87% (95% CI: 60%, 96%) between 14 and 179 days after the last dose and 81% (95% CI: 51%, 92%) ≥180 days after the last dose. This model was adjusted for age (as a continuous variable), extreme vulnerability status, the group of municipalities of residence and the calendar month of testing (Table 3).

The Hosmer–Lemeshow test yielded *P*-values of 0.195 and 0.633 for the symptomatic and severe disease models, respectively. Therefore, this study could not exclude the hypothesis of the models having a good fit.

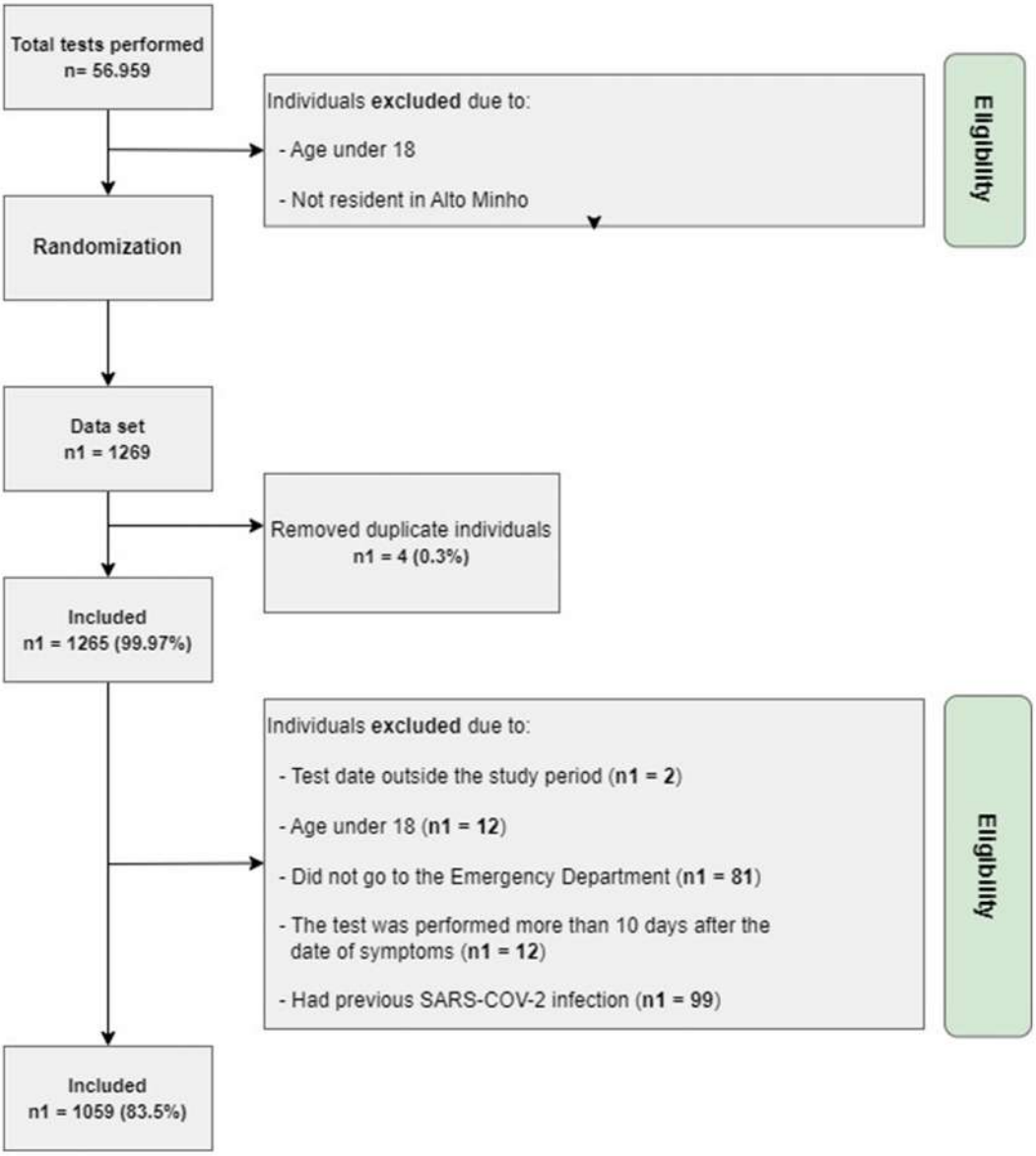

Fig. 1. Flowchart of the included and excluded individuals. A sample was randomly selected from the total tests performed between 1 June 2021 and 2 March 2022 ($N = 56{,}959$).

A statistically significant interaction was found in the severe disease model between age and the group of municipalities of residence (Table 3).

The magnitude of missing data was low (9%). Most missing data were observed on the date of symptom onset (7%); missing observations were completed with the test date. As there were a few missing observations, this was unlikely to impact the results.

Discussion

In this analysis, the absolute effectiveness of a booster was superior to that of the primary series and was even higher when the last inoculation was ≥180 days. In the study population who completed the primary series more than six months earlier, the booster prevented 71 of 100 symptomatic infections that would have occurred in the absence of a booster.

The mRNA vaccines (BNT162b2 and mRNA-1273) provided superior protection against symptomatic disease over the viral vector vaccines, although the result was not statistically significant.

Having an extremely vulnerable status was considered a confounder in the model of severe outcomes. Table 3 shows that being extremely vulnerable (as a result of immunosuppression and/or severe respiratory diseases, among other criteria described elsewhere)[16] is a risk factor for severe disease.

The residents in Vale do Minho showed a reduced risk of infection (adjusted OR = 0.50) but an increased risk of severe disease (adjusted OR = 3.54) compared with the residents in Vale do Lima. Vale do Minho is a more rural part of Alto Minho and is inhabited by older people who are usually less exposed to the virus but who can develop complications and more severe diseases. However, as the model was adjusted for age, an external factor may explain these differences, such as the access to health care, which may be compromised for residents in Vale do Minho, as the two hospitals in Alto Minho are located in Vale do Lima.

Despite the known characteristics of immunological evasion of the Omicron variant, the results of the present study show that vaccine effectiveness increased after booster vaccination, which is consistent with results from other studies.[9,20] Furthermore,

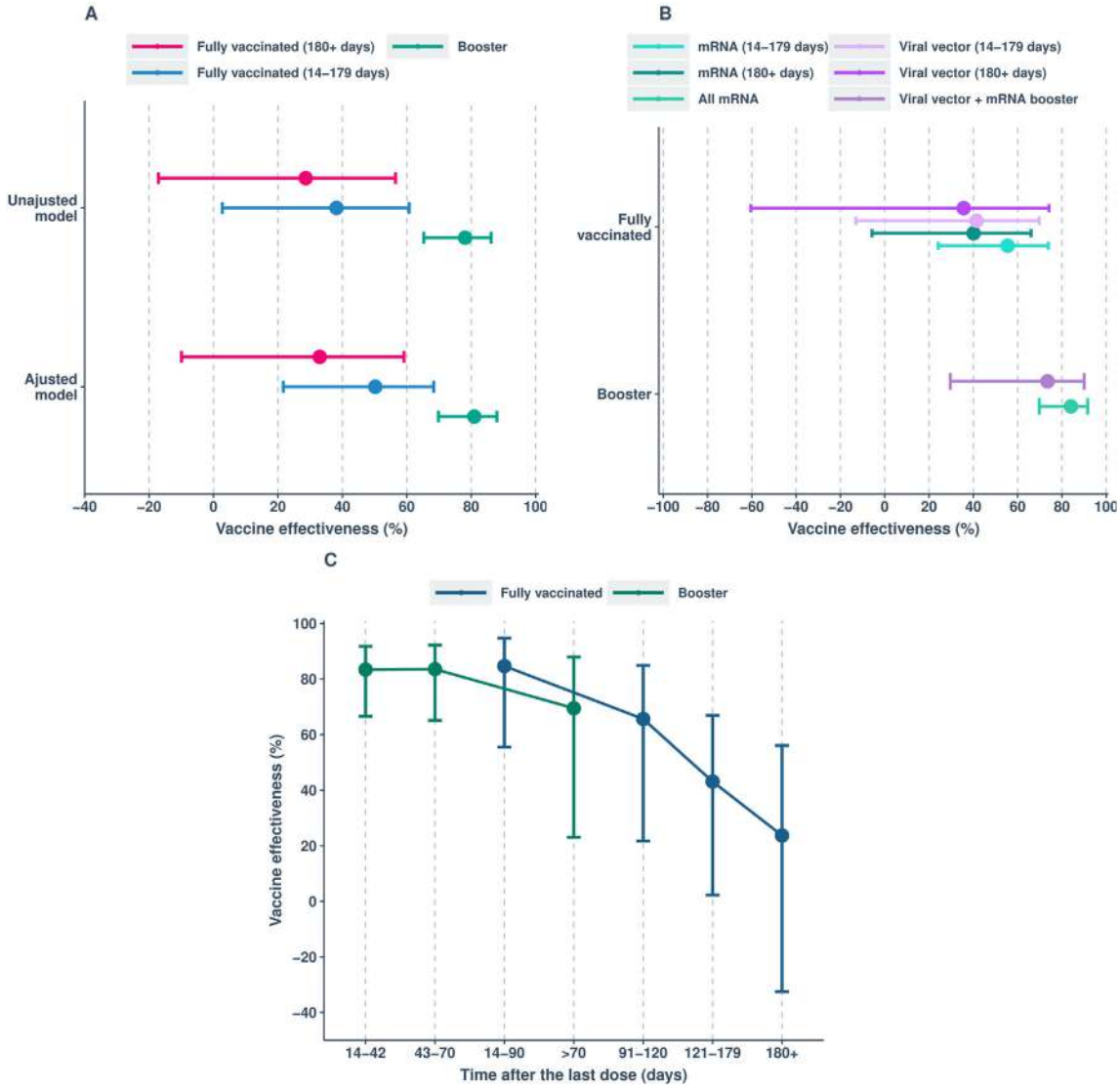

Fig. 2. Scree plot of the vaccine effectiveness for symptomatic infection in the fifth pandemic wave: A – Fully vaccinated (i.e. primary series only) vs. booster, stratified by time since the last vaccine dose. B – Fully vaccinated (i.e. primary series only) vs. primary series + booster, stratified by time since the last dose and type of vaccine (mRNA vs viral vector vaccines). C – Waning of vaccine effectiveness stratified by time after the last dose. Models adjusted for age and the group of municipalities of residence.

immunological studies suggest that there is an increase in immune response after the second dose, including a rise in the concentration and adaptation of the anti-receptor binding domain, specific for memory B cells, which confers biological plausibility for a higher vaccine effectiveness after booster vaccination, even with a highly divergent variant such as Omicron.[21–24]

The present study results also add to the accumulating evidence of the waning of vaccine protection over time for the primary series.[24,25] The effectiveness decreased to less than 50% between the third and sixth months after the last dose, so this may be the most appropriate time for booster administration.

The present study suggests that COVID-19 is less likely to result in hospitalisation, I/ICU admission and/or death in patients inoculated with a booster than in those who received only the primary scheme.

Strengths and limitations

The present study design has the following substantial strengths: (1) the cases and controls were recruited from the same healthcare unit and resided in the same geographical area, reducing bias due to risk variation according to locality;[15] (2) the cases and controls all sought care for a defined set of symptoms, which lowers the probability of health-seeking bias, an advantage of the study compared with traditional case–control and cohort studies;[15,26,27] (3) the vaccination status is usually recorded before knowing the test result, avoiding a potential differential misclassification bias;[15] and (4) the Local Health Unit of Alto Minho provided resident-level demographic and clinical data, allowing the study to analyse more detailed and complete data.

Some weaknesses of the study must also be considered, mainly due to its observational nature. There may be confounding when the vaccination status is associated with the risk of SARS-CoV-2 exposure. If, for instance, individuals who choose not to be vaccinated are also those who do not adhere to individual protective measures, this may lead to an overestimation of the vaccine effectiveness. Meanwhile, vaccinated individuals may exhibit more risky behaviours by believing they are protected, resulting in an underestimation of the vaccine effectiveness.[15] The sensitivity of PCR tests is not 100%, which may have led to the misclassification of

Table 2
Multivariable logistic regression model for symptomatic infection.

Variables	Symptomatic infection model		
	OR	95% confidence interval	*P*-value
Vaccination status			
Unvaccinated	Ref.	Ref.	Ref.
Fully vaccinated (14–179 days)	0.50	(0.31–0.82)	0.006[a]
Fully vaccinated (≥180 days)	0.66	(0.39–1.12)	0.123
Booster	0.19	(0.11–0.32)	<0.001[a]
Age (cubic spline with 3 DF)			
Component 1	0.63	(0.33–1.22)	0.169
Component 2	0.51	(0.15–1.74)	0.281
Component 3	0.28	(0.14–0.55)	<0.001[a]
Residence			
Vale do Lima	Ref.	Ref.	Ref.
Vale do Minho	0.52	(0.33–0.81)	0.003[a]
Month			
November	Ref.	Ref.	Ref.
December	1.25	(0.81–1.94)	0.317
January	3.51	(2.15–5.71)	<0.001
February	3.00	(1.79–5.05)	<0.001
March[b]	<0.001	(0–inf)	0.973

OR: odds ratio. Ref: reference.
[a] Statistical significance for $\alpha = 0.05$.
[b] Data were only analysed until March 2; therefore, we only had few observations in March, all of which were controls, rendering the confidence interval for this month to be wide.

Table 3
Multivariable logistic regression model for severe disease.

Variables	Severe disease model		
	OR	95% confidence interval	*P*-value
Vaccination status			
Unvaccinated	Ref.	Ref.	Ref.
Fully vaccinated (14–179 days)	0.13	(0.05–0.40)	<0.001[a]
Fully vaccinated (≥180 days)	0.19	(0.08–0.49)	<0.001[a]
Booster	0.10	(0.04–0.30)	<0.001[a]
Age	1.08	(1.06–1.10)	<0.001[a]
Group of municipalities of residence			
Vale do Lima	Ref.	Ref.	Ref.
Vale do Minho	<0.001	(0.001–25)	0.140
Group of municipalities of residence by age			
Vale do Lima	Ref.	Ref.	Ref.
Vale do Minho	1.18	(1.03–1.51)	0.008[a]
Extremely vulnerable status			
No	Ref.	Ref.	Ref.
Yes	4.49	(2.00–10.13)	<0.001[a]
Month			
November	Ref.	Ref.	Ref.
December	0.25	(0.09–0.70)	0.008[a]
January	0.37	(0.13–1.08)	0.069
February	0.34	(0.11–1.03)	0.056

OR: odds ratio; Ref: reference.
[a] Statistical significance for $\alpha = 0.05$.

cases in either of the controls and consequently may have attenuated the vaccine effectiveness estimates. In addition, the sample size precluded distinguishing the vaccine effectiveness among the more severe outcomes of COVID-19 – ICU admission and death. It was also difficult to directly measure the vaccine effectiveness against specific virus variants owing to the low proportion of genotyped cases. Nevertheless, this study analysed periods when different variants were dominant; thus, the study had an approximated vaccine effectiveness against these variants indirectly.

The present study was conducted primarily in the context of the Omicron sublineage BA.1. The sublineage BA.2 became dominant in the last week of the study period, and its prevalence increased in many areas of the world, indicating a likely competing advantage compared with BA.1. Nevertheless, recent evidence suggests that this advantage is related mainly to increasing transmissibility rather than to a higher immunity evasion.[28–30] Therefore, theoretically, the present study results would have been the same in the context of BA.2.[31]

The present results may not be representative of the wider general population, including people who are less prone to seek medical care in case of symptoms (e.g. ethnic minorities or people living in deprived areas). Although many relevant confounders were controlled in the models of vaccine effectiveness, residual or unmeasured confounding may have occurred.

The present study was restricted to the analysis of the first booster, as the second booster was approved in Portugal only after the study period. Future studies on the second booster are necessary.

Conclusions

This study has shown that vaccine effectiveness increases after booster administration. The optimal time for booster administration is between 3 and 6 months after completion of the primary cycle as this is the time when vaccine effectiveness decreases to less than 50%.

Author statements

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Ethical approval

The Ethics Committee of the Local Health Unit of Alto Minho (ULSAM) approved the protocol of this study with the reference number 05/2022. We followed STROBE guidelines, as can be seen in the supplementary material. The ethical principles of human medical research contained in the Declaration of Helsinki and national legislation were respected. The data collected were anonymised, guaranteeing the necessary confidentiality of the information collected. In addition, the principal investigator and her supervisors are subjected to medical confidentiality according to the Code of Ethics of the Portuguese Medical Association.

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Competing interests

None declared.

Author contributions

Conceptualisation, C.B., A.A. and R.D.; methodology, C.B., A.A., M.P. and F.A.; writing – original draft preparation, C.B.; writing – review and editing, all authors; supervision, R.D., M.P., A.A. and L.S. All authors have read and agreed to the published version of the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2023.02.015.

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Evaluation of the national governmental efforts between 1997 and 2010 in reducing health inequalities in England

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ABSTRACT

Objectives: The pandemic has compounded existing inequalities. In the UK, there have been calls for a new cross-government health inequalities strategy. This study aims to evaluate the effectiveness of national governmental efforts between 1997 and 2010, referred to as the National Health Inequalities Strategy (NHIS).

Study design: population-based observational study.

Methods: Using Global Burden of Disease data, age-standardised years of life lost due to premature mortality (YLL) rates per 10,000 were extracted for 150 Upper Tier Local Authority (UTLA) regions in England for every year between 1990 and 2019. The slope index of inequality was calculated using YLL rates for all causes, individual conditions, and risk factors. Joinpoint regression was used to assess the trends of any changes which arose before, during or after the NHIS.

Results: Absolute inequalities in YLL rates for all causes remained stable between 1990 and 2000, before decreasing over the following 10 years. After 2010, improvements slowed. A similar trend can be observed amongst inequalities in YLLs for individual causes, including ischaemic heart disease, stroke, breast cancer and lung cancer amongst females, and ischaemic heart disease stroke, diabetes and self-harm amongst males. This trend was also observed amongst certain risk factors, notably blood pressure, cholesterol, tobacco and dietary risks. Inequalities were generally greater in males than in females; however, trends were similar across both sexes. The NHIS coincided with significant reductions in inequalities in YLLs due to ischaemic heart disease and lung cancer.

Conclusions: The findings suggest that the NHIS coincided with a reduction in health inequalities in England. Policy makers should consider a new cross-government strategy to tackle health inequalities drawing from the success of the previous NHIS.

Introduction

During 2017 to 2019, the gap in life expectancy between the most and least deprived regions in England was 11.3 years for males and 8.7 years for females.[1] Between 2003 and 2018, approximately one third of deaths in England were attributable to socio-economic inequality.[2] Annually, health inequalities account for productivity losses of approximately £31–33 billion, whilst costs incurred to the NHS amount to more than £5.5 billion.[3] The COVID-19 pandemic has both revealed and exacerbated the stark health inequalities which persist across society.[4]

There is a significant lack of evidence surrounding both the type of policies and methods of implementation most likely to decrease health inequalities.[5] To develop a successful strategy, there is an urgent requirement to better understand past successes and failures. The creation of the NHS in 1948 is often considered the first serious effort to address health inequalities.[6] However, the 13-year systematic attempt to reduce health inequalities in England, between 1997 and 2010, is generally considered the county's most comprehensive attempt to do so.[7,8] The total budget exceeded £20 billion.[7,9]

Overall, consensus as to the effectiveness of the strategy remains unclear.[10] A formal review – Tackling Health Inequalities: 10 Years

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On[11] – by the Department of Health in 2009 acknowledged significant improvements in the health of the population and that the majority of departmental commitments set out in the Programme for Action had been met. Average life expectancy for all groups increased significantly across the whole population, but improvements were lower in the target areas. Early reports[12,13] concluded that whilst the strategy could be considered partially successful, in that reductions in health inequalities were observed between 1997 and 2010, the specific targets outlined in the strategy were not met. Later findings were more encouraging. Time-trend analysis found that geographical health inequalities in life expectancy decreased marginally during the strategy period, temporarily reversing the previously increasing trend, but inequalities since 2010 have widened.[14] A recent study[15] found that geographical inequalities in infant mortality rate increased before the strategy and decreased throughout the strategy, with no evidence that this decrease in inequality continued after the strategy. The increase in proportion of NHS resources allocated to deprived areas between 2001 and 2011 was associated with a reduction in absolute health inequalities from causes amenable to healthcare.[16]

We evaluate the effectiveness of efforts to reduce health inequalities between 1997 and 2010, referred to broadly as the National Health Inequalities Strategy (NHIS). We investigate changes in socio-economic health inequalities before, during and after the implementation of the strategy measured by premature mortality.

In doing so, we address two gaps within the current literature. Whilst analysis to date has highlighted wider condition groups which may have seen improvements in health inequality indicator, tracking trends in health inequalities over time for individual causes before, during and after the strategy has yet to be explored. Second, analysis to date has employed a range of methods of health inequality measurement yet neglected to utilise well-established indices of inequality such as the slope index of inequality (SII).

Methods

Led by the Institute for Health Metrics and Evaluation (IHME), the Global Burden of Disease (GBD) study is a comprehensive worldwide observational epidemiological study enabling the systematic assessment of local, regional, national and international trends in health. Detailed methods have been described elsewhere.[17,18] In brief, the GBD study adopts a standardised analytical approach for estimating life expectancy, years of life lost due to premature mortality (YLLs) and risk factors. It captures data for more than 350 diseases and injuries, by age and sex, from 1990 to present.[19] In England, the GBD study reports data for 150 Upper Tier Local Authority (UTLA) regions, reflecting a total population of approximately 56 million people, including county councils, London boroughs, unitary authorities and metropolitan districts.[17,19]

Age-standardised YLL rates per 10,000 were extracted for 150 UTLA regions in England for every year between and inclusive of 1990–2019, for all causes, individual conditions and risk factors. YLLs are mapped to cause, age and sex groups in the GBD study based on a based upon a four-level hierarchy.[19] YLLs were compared at level 3 to ensure a meaningful and insightful level of analysis. Conditions that would be included in the analysis were determined a priori, informed by the wider research advisory panel consisting of clinicians, public health professionals, and health policy makers. Broadly, conditions were chosen to align with the areas which the strategy aimed to have a specific impact on.

The SII was used to measure inequalities in YLLs. The SII reflects differences in health status between two hypothetical individuals, one at the top and bottom of the socio-economic distribution, respectively.[20] The SII accounts for the social gradient in health[21–24] and is sensitive to the mean health status of a population and distribution of population across different socio-economic groups.[22]

The Index of Multiple Deprivation (IMD) is the official measure of relative deprivation in England, broadly defining deprivation by accounting for a range of factors which relate to an individual's living conditions.[25] IMD ranks were assigned to all 150 UTLA regions for each year between 1990 and 2019. We applied the 2004 IMD Rank for each UTLA region across all years to assess changes from this baseline. Linear regression analysis of all-cause and individual conditions, risk factors, and age-standardised YLL rates per 10,000 individuals by IMD decile was conducted. In each case, the coefficient of the regression was the SII, which reflected the absolute change in YLL rates that occur with every single unit increase in IMD decile. The primary outcome measures were absolute inequalities, measured by the SII, in age-standardised YLL and rates for all causes, individual conditions and risk factors, by sex for each year from 1990 to 2019. All analyses were conducted in STATA 16.1. Joinpoint regression analysis[26] detected the time at which a statistically significant change in the trend of the data was observed, using a series of permutation tests. The analysis was performed for all-cause YLL rates, for both males and females, allowing up to two join points utilising a Monte Carlo permutation method. The analysis was conducted using the Join point regression program from the Surveillance Research Program of the National Cancer Institute Version 4.2.0.2 (Statistical Research and Applications Branch, National Cancer Institute, US).[26]

Results

All causes

Table 1 and Fig. 1 display the change in the SII for all cause YLLs. In general, inequalities in YLLs were higher amongst males than in females. For both females and males, health inequalities increased initially before decreasing from approximately 1996 onwards. After

Table 1
SII for Age-standardised YLLs (rate per 10,000) in 150 UTLA regions in England, Male and Female, 1990–2019.

Year	**Total**				
	SII	*SE*	*P-value*	*(Lower CI)*	*(Upper CI)*
1990	−596	26	<0.00	−648	−544
1995	−626	25	<0.00	−675	−578
2000	−593	23	<0.00	−638	−548
2005	−526	24	<0.00	−574	−478
2010	−434	24	<0.00	−481	−386
2015	−394	26	<0.00	−446	−342
2019	−370	29	<0.00	−427	−314
	Female				
Year	*SII*	*SE*	*P-value*	*(Lower CI)*	*(Upper CI)*
1990	−411	20	<0.00	−450	−371
1995	−411	18	<0.00	−446	−375
2000	−420	18	<0.00	−456	−385
2005	−364	21	<0.00	−405	−323
2010	−312	20	<0.00	−352	−273
2015	−290	23	<0.00	−335	−244
2019	−263	22	<0.00	−307	−219
	Male				
Year	*SII*	*SE*	*P-value*	*(Lower CI)*	*(Upper CI)*
1990	−825	38	<0.00	−900	−750
1995	−884	38	<0.00	−958	−809
2000	−793	31	<0.00	−854	−731
2005	−708	31	<0.00	−769	−647
2010	−566	30	<0.00	−626	−506
2015	−504	32	<0.00	−567	−441
2019	−483	37	<0.00	−557	−410

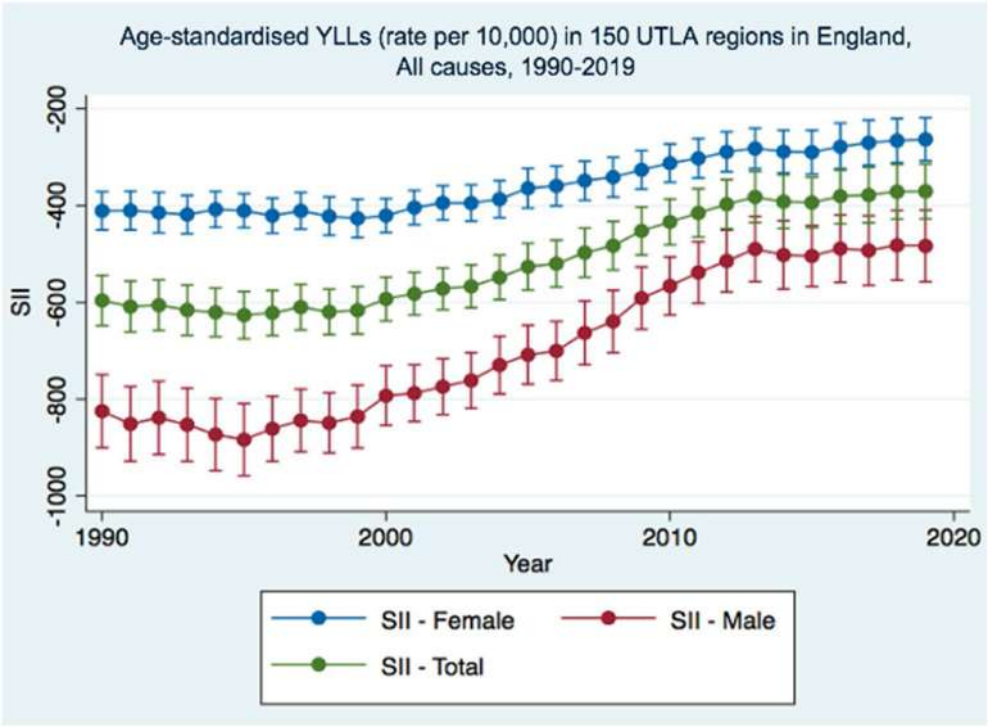

Fig. 1. SII for Age-standardised YLLs (rate per 10,000 with 95%CI) in 150 UTLA regions in England, All causes, 1990–2019.

2010, improvements in health inequalities continued at a slower rate. Joinpoint regression analysis showed that inequalities narrowed, particularly between 1996 and 2013, supporting the findings in linear regression analysis. Amongst males, females and both sexes combined, there was a statistically significant change in trend in SII between 2012 and 2013 for YLLs. This is reflective of a general trend in the years following 2010, whereby improvements in health inequalities began to plateau (see Table 2).

Individual conditions and risk factors

In general, the most substantial inequalities in YLL rates amongst females were observed in ischaemic heart disease, stroke, neonatal preterm birth, lower respiratory infections and COPD, as shown in Fig. 2. Age-standardised YLL rates for ischaemic heart disease were significantly greater than all other conditions and are presented separately in Fig. 3. Inequalities in YLL rates improved over time for stroke, neonatal preterm birth, lower respiratory infections, diabetes and self-harm. Inequalities in YLLs due to COPD, drug use disorders and cirrhosis and other chronic liver diseases showed little improvement and even deteriorated between some years. Amongst males, ischaemic heart disease, COPD, stroke and lower respiratory infections had the most significant inequalities in YLLs. Inequalities in YLL rates for ischaemic heart disease, COPD, stroke and lower respiratory infections reduced significantly between 1990 and 2019. Inequalities in YLL rates for drug use disorders, self-harm and neonatal preterm birth showed comparatively minimal improvements in reductions between 1990 and 2019.

Amongst females, inequalities in YLLs were comparatively low in colorectal and pancreatic cancer, with little fluctuation in SII observed between 1990 and 2019. Inequalities in YLL rates per 10,000 for both breast and lung cancer increased between 1990 and 2000, before steadily decreasing between 2000 and 2019. Amongst males, absolute inequalities for colorectal, prostate and pancreatic cancer were minimal and showed little variation over time. Inequalities in YLL rates due to lung cancer were more significant yet improved steadily over time and had almost halved by 2019, as shown in Fig. 4.

In general, the SII increased steadily over time for cholesterol, tobacco, dietary risks and blood pressure, with reductions in inequalities in YLL rates broadly coinciding with the strategy period, shown in Fig. 5. This increase in SII was most dramatic amongst males, particularly for tobacco, suggestive of a significant reduction in inequalities in YLLs between the most and least deprived regions throughout the strategy period. The SII remained relatively constant amongst alcohol use, child and maternal malnutrition, physical activity and drug use, with little variation between sexes and minimal absolute inequalities observed more generally since 1990.

Table 2
Joinpoint regression analysis, Age-standardised YLLs (rate per 10,000), All causes

Total				
Joinpoint	*Estimate*	*Lower CI*	*Upper CI*	*Slope change*
1	1999	1997	2001	−0.76
2	2013	2009	2015	0.45
Female				
Joinpoint	*Estimate*	*Lower CI*	*Upper CI*	*Slope change*
1	2000	1998	2001	−11.85
2	2012	2010	2014	6.49
Male				
Joinpoint	*Estimate*	*Lower CI*	*Upper CI*	*Slope change*
1	1998	1995	2000	−27.41
2	2013	2011	2015	21.02

Discussion

Statement of principal findings

Findings suggest that the NHIS coincided with a reduction in inequalities in YLL rates. Broadly, total inequalities in YLLs remained

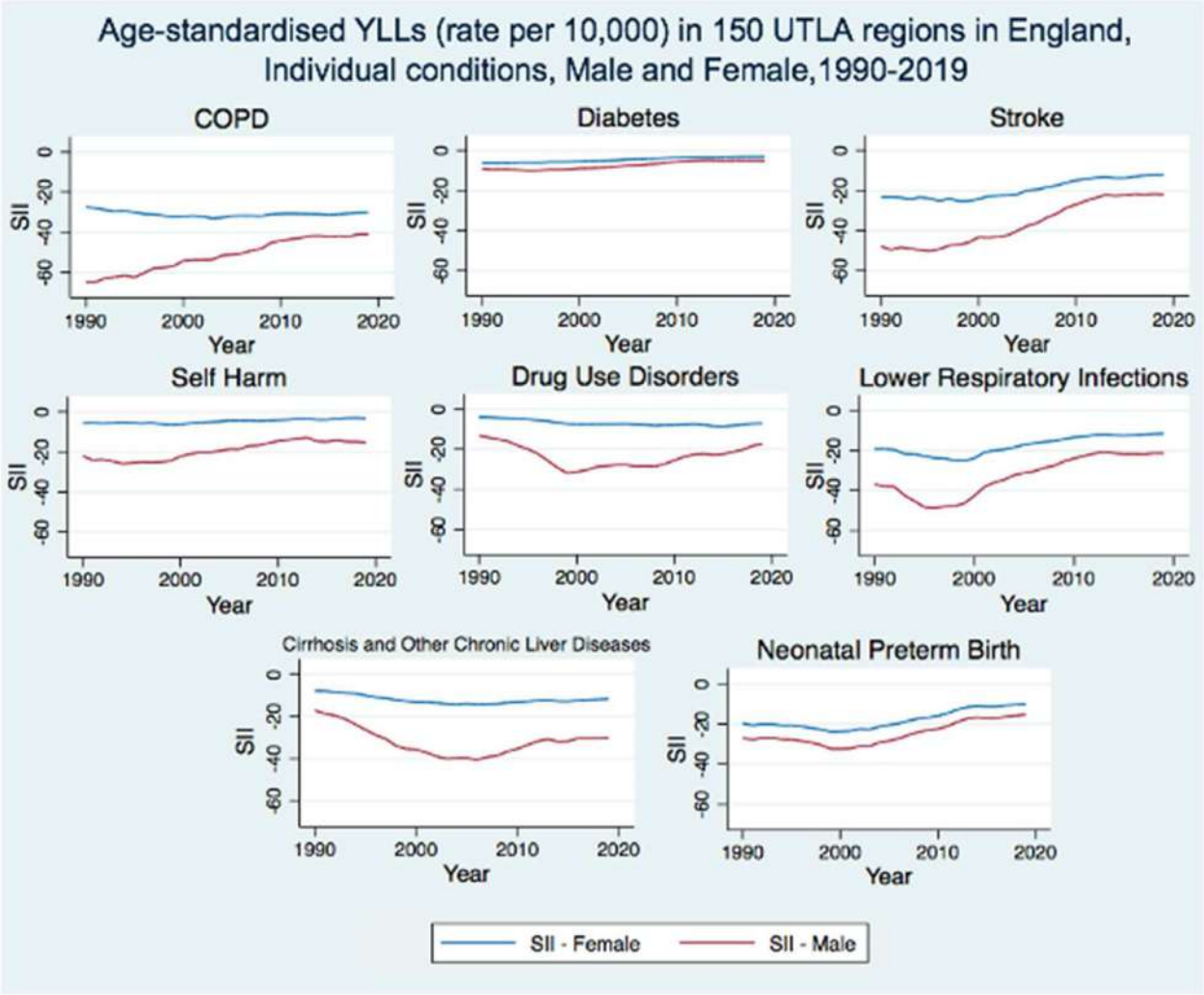

Fig. 2. Age-standardised YLLs (rate per 10,000 with 95%CI) in 150 UTLA regions in England, Individual conditions, Male and Female, 1990–2019.

relatively stable between 1990 and 2000, significantly improved over the following 10 years, and began to plateau in the years following the end of the strategy. This pattern is observed across both males and females although it is particularly evident in males. A similar trend can be observed amongst inequalities in YLLs for individual causes, including ischaemic heart disease, stroke, breast cancer and lung cancer amongst females, and ischaemic heart disease stroke, diabetes and self-harm amongst males. This trend was also observed amongst certain risk factors, notably blood pressure, cholesterol, tobacco and dietary risks.

The years following the strategy saw reduced improvements in inequalities. It is possible that the tendency for inequalities in YLL and mortality rates to plateau in 2010 was due in part to the 2008 financial crisis. Reduced improvements in life expectancy were observed in England from 2011 onwards,[27] which may have simultaneously resulted in the observed levelling off of improvements in health inequalities. There is also evidence to suggest that the substantial increase in public expenditure on the health system which coincided with the NHIS was a major factor driving reductions in health inequalities between 2001 and 2010 (16). Levelling off in subsequent years may have been a result of subsequently implemented financial constraint measures.

Whilst we found that the NHIS was associated with a reduction in health inequalities, there are other potential factors, especially when potential lag effects are considered. Before 2008, there was a period of sustained economic growth with a rise in living standards and there continued to be an expansion of healthcare interventions which may have contributed to overall improved health, with a greater improvement in lower socio-economic groups. Alternatively, the improvements may have been related to other government action not related to the NHIS. However, changes in these factors are not consistent with the start and end of the change in trend, and the NHIS was a cross-government effort and it is difficult to argue that it did not influence every aspect of government.

Strengths and limitations

By measuring absolute health inequalities, we provide useful, interpretable data and insights regarding how inequalities in health have changed over time. The use of GBD data allowed the identification of trends for individual conditions and risk factors. These findings may suggest which direct healthcare or public health interventions may have been the most successful aspects of the strategy. Less clear conclusions can be drawn concerning which actions on the wider determinants of health were more instrumental, given their interacting, complex and indirect effects on both a public health intervention's effectiveness and on a population's health. The comprehensive GBD dataset allowed analysis

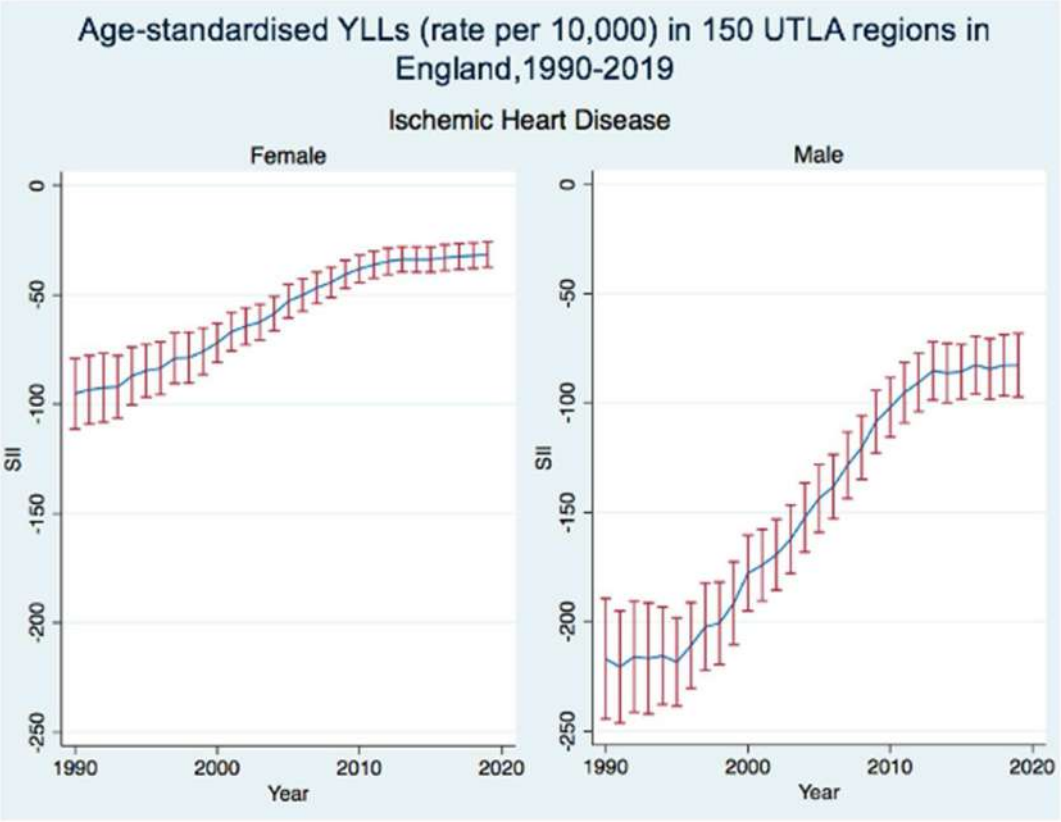

Fig. 3. SII, age-standardised YLLs (rate per 10,000 with 95%CI), ischaemic heart disease, female and male, 1990–2019.

using data over a 30-year period from 1990 to 2019, and present the most comprehensive longitudinal analysis to date. The use of the SII as a measure of health inequality assesses inequalities across the whole population rather than just groups at the most extreme ends. Moreover, which every healthcare system and wider health policy agenda is naturally unique, the methods used in this analysis could be used to assess other nation's progress in reducing health inequalities over time.

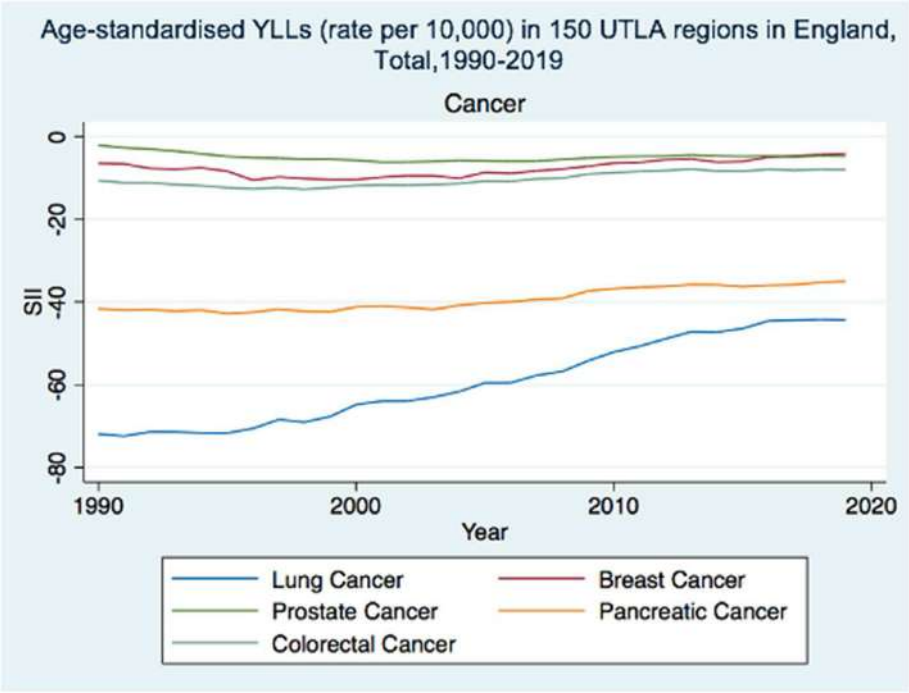

Fig. 4. SII, age-standardised YLLs (rate per 10,000 with 95%CI), cancer, total, 1990–2019.

This study is also subject to several limitations. As the IMD is a composite measure comprised of seven indicators, one of which includes health, it is possible that the strong statistically significant negative correlation between YLLs and deprivation, may be an overestimation of the true association. However, as removing the health component of the IMD has little to no effect on the overall association between two health variables,[28] this is unlikely to influence findings. The level of geographical granularity of our analysis was also limited to the level provided within the GBD study and associated IMD rank. The use of large area estimates has several implications, including ecological fallacy whereby all individuals who live in the same area are assigned to the same level of deprivation, which is unlikely to be the case given the large populations within UTLA regions. The primary limitation of the use of GBD data in the UK is the potential biases arising from the statistical modelling process, including the impact of numerous decisions made at this stage which generally remains unclear. GBD also relies on data from a variety of sources, including vital registration systems, household surveys and hospital records. Whilst data availability in the UK remain comprehensive, it is likely this varied across the 30 years of data used in this study.isk factor data in particular are subject to several biases and are dependent on the underlying quality of data.[29] The GBD uses statistical modelling techniques to estimate health outcomes in countries where data are scarce or missing. Whilst these methods are generally robust, they are subject to uncertainty, and estimates may not always be precise. Whilst the data availability in the UK means that this is not necessarily a significant limitation, UK data are still modelled to ensure international comparability which may lead to biases. ause-specific YLL data in particular are subject to the reallocation of ill-defined death codes. Moreover, whilst the GBD covers a wide range of diseases, injuries, and risk factors, it does not include all health outcomes and it is likely that some conditions such as rare diseases or mental health disorders, may be misrepresented. Whilst the aim of this analysis was to investigate changes in absolute health inequalities using the SII, we do not know the impact of the NHIS on relative inequalities.[30] It is conceivable that changes in absolute inequalities throughout this period may not have reflected the same trend as relative inequalities. The generalisability of the findings is limited in that trends in health inequalities were analysed within the context of the wider society and situational factors present in England between 1990 and 2019. Given the contextual

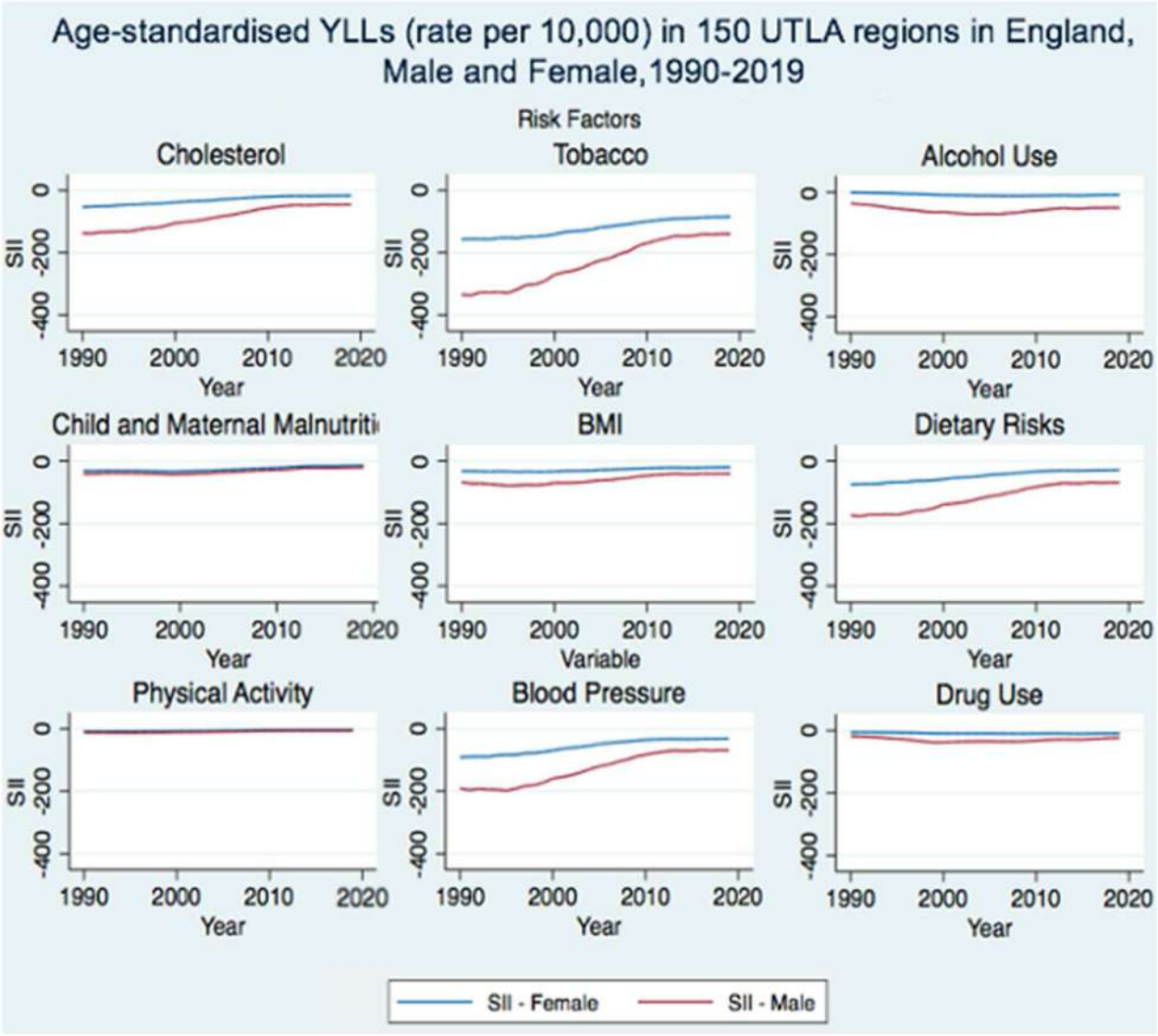

Fig. 5. SII, age-standardised YLLs (rate per 10,000 with 95%CI) in 150 UTLA regions in England, male and female, 1990–2019.

factors in relation to time and place, care must be taken when generalising the findings to different countries.

Comparison to existing literature

The all-cause findings support early studies[12,13] suggesting that the strategy was partially successful in reducing health inequalities, with reductions in health inequalities observed between 1997 and 2010. The findings, particularly those from the Join point regression analysis, align more generally with previous studies[3,14] that suggest that inequalities amongst certain health indicators decreased marginally during the strategy period, temporarily reversing the previously increasing trend, but plateaued or widened from 2010 onwards. Here, we add to the existing literature by undertaking a condition-specific analysis. Moreover, the use of the SII represents a novel methodological contribution, with analysis to date having employed a range of methods of health inequality measurement yet neglected to utilise well-established indices of inequality such as the SII.

Public health and policy implications

This research provides strong evidence that the implementation of a new cross-government strategy to tackle health inequalities has the potential to significantly reduce health inequalities in England. The analysis highlights the importance of accounting for the mechanism through which an individual policy is expected to infer or create an impact. Naturally, we would expect conditions such as drug use disorders to have a longer 'gestation' period between time from policy implementation to impact. When developing target and monitoring dates for a national health inequalities strategy, consider the time through which we would reasonably expect to see an impact, which will differ across individual conditions and risk factors.It remains an unfortunate reality that health policy is often driven by the electoral cycle, whereby interventions that are likely to have a short-term impact are more likely to be commissioned. A greater acceptance of long-term vision is required to ensure inequalities amongst conditions and risk factors with a longer "time to impact" are not neglected. The findings highlight that despite some success in reducing absolute inequalities in YLLs and mortality for conditions including lung cancer and ischaemic heart disease, significant disparities between the most and least deprived regions in England continue to persist.

Further research

The impact of the NHIS was not observable until years after implementation; therefore, it is imperative that future policy evaluations look over the long term. More research is need to explore whether the implementation of the NHIS reduced inequalities to a greater or lesser extent across certain geographical areas, including coastal communities and in north of the country would be useful in order to determine areas which may require a greater investment of resources in the future. In addition, further investigation could assess the NHIS's impact in London given differing health inequality trends in London compared to the rest of the country.[31]

Conclusion

The trends in inequalities in YLL rates reflected through the SII for all causes, individual conditions and risk factors collectively suggest that the NHIS coincided with a reduction in health inequalities between 1997 and 2010. The analysis sheds light on what specific reductions in inequalities across individual conditions and risk factors could be attributed to this observed trend, and highlights similarities and differences in changes in inequalities amongst males and females. This study provides strong evidence to suggest that the development of a new cross-government strategy to tackle health inequalities has the potential to significantly reduce health inequalities in England.

Author statements

Ethical approval

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Competing interests

None declared.

Data availability

No data available.

Individual author contribution

JF conceptualised the study. AV and JF drafted the protocol and CB, LM, BB and EM provided comments. AV conducted the data analysis and wrote the first draft of the manuscript. All co-authors provided comments. AV, IH and JF redrafted. All authors approved the final version.

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Original Research

Health-related quality of life in Welsh adults: psychometric properties of the SF-36v2 and normative data

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ABSTRACT

Objectives: The use of normative data has become well-accepted and a common strategy to interpret individual's health outcome scores, which can help in making decisions. The objectives of this study were to obtain population normative data for the domains and component summaries of the 36-item SF-36® Health Survey (SF-36), and to evaluate its reliability and construct validity.

Methods: This study was conducted using population-based data from the Welsh Health Survey (WHS; 2011–2015). This study used version 2 of the SF-36 (SF-36v2® Health Survey). The descriptive statistics and normative data for the eight domains and two summaries, physical component summary (PCS) and mental component summary (MCS), were calculated. Reliability assessment used internal consistency methods and construct validity assessment used known group comparisons and item–scale correlations.

Study design and sample: We performed a secondary analyses of data from the Welsh Health Survey (WHS).

Results: This study included 74,578 participants aged 16 years or older (53.6% were women). Participants aged 16–24 years scored higher on SF-36 scale than older groups on all domains. The SF-36 profiles by age group demonstrated lower scores for older age groups, with the most pronounced differences shown on the physical-related scales. Across the age groups, men had higher PCS and MCS scores than women. All SF-36 domains and PCS and MCS achieved a good to excellent internal consistency reliability exceeding 0.7. The scales demonstrated construct validity by showing associations with a range of factors known to be related to health.

Conclusions: This study provides SF-36 normative data for Wales based on a representative data and confirms the construct validity and reliability of the SF-36.

Introduction

There has been growing interest in research related to the quality of life – from both an individual and a societal level. Health-related quality of life (HRQoL) is a multifaceted construct involving dimensions of life related to physical, mental, and social aspects.[1–3] HRQoL refers to individual's subjective reports of well-being and functioning in various domains of life including physical, mental, and social health. Well-being includes positive and negative aspects, such as feeling happy, energic, sad, anxious, fatigued, or in pain. Functioning involves physical functioning (e.g., self-care), role functioning (e.g., work activities), and social functioning (i.e., the extent of interpersonal relationships).[4,5] In addition to health

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status, HRQoL can be influenced by other factors such as sex, age, or educational level.[1,2,6–8] As there are differences in these factors between populations, HRQoL score differences are also expected.

The use of normative data has become well-accepted and a common strategy that is used to interpret scores of individual's health outcomes, which can help in making decisions.[9] Normative data derived from a valid and well-defined sample of the general population is essential to interpret findings from specific patient populations.[10] The 36-item SF-36® Health Survey (SF-36) has been widely used to assess HRQoL.[1,3,7,11] It was developed in the Medical Outcomes Study (MOS) to include only the most important aspects of quality of life that were frequently used in health surveys or affected by disease and treatment.[3,11]

Available normative data for the SF-36 from countries such as USA,[1] Canada,[7] Norway,[6] and Switzerland[2] demonstrate differences between countries in terms of structure of the data, participants' characteristics, sample size, and statistical analysis. In the UK, a study by Burholt & Nash[8] in the Wales regions is the latest available study to provide population norms for the SF-36. However, this study used a data set that is over 10 years old (obtained in 2007), which might be no longer representative for the current population. HRQoL levels can change over time.[12] Therefore, up-to-date data on HRQoL is a help in interpretation. Against this background, it is beneficial to conduct a comprehensive study with more recent normative data in a larger sample to accurately assess the quality of life in individuals living in Wales, UK.

The objectives of this study were (1) to obtain population normative data for the domains and component summaries of the SF-36, and (2) to evaluate reliability and construct validity of the SF-36.

Methods

Study sample

This study was conducted using population-based data from the Welsh Health Survey (WHS; 2011–2015). The WHS included 74,578 individuals aged 16 years and older.

The WHS is a survey administered using face-to-face interview with participant in their household by using a self-complete paper questionnaire. It is conducted annually to measure the health status of the general population living in Wales, UK. The WHS recruited participants using multistage, stratified probability sampling, with postcode sectors selected at the first stage, and household addresses selected at the second stage. More details about the survey can be found at NatCen Social Research.[13] Ethical approval for the WHS was granted by the NatCen Social Research Ethics Committee in London, UK. The data were anonymized and are available to bona fide researchers through the UK Data Archive (http://data-archive.ac.uk/). The present study has been carried out and reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[14]

SF-36v2 health survey

The SF-36 is a self-reported health survey that assesses HRQoL in eight domains: physical functioning (PF, 10 items), role-physical (RP, 4 items), bodily pain (BP, 2 items), general health (GH, 5 items), vitality (VT, 4 items), social functioning (SF, 2 items), role-emotional (RE, 3 items), and mental health (MH, 5 items).[15] This study used version 2 of the SF-36. In traditional scoring, scores for each domain range from 0 to 100, with higher scores representing better HRQoL.[16] From the eight domains, the physical component summary (PCS, mainly based on PF, RP, BP, and GH) and the mental component summary (MCS, mainly based on VT, SF, RE, and MH) are constructed and standardized to a mean of 50 and a standard deviation of 10 in the US general population, with higher scores indicating better health.[11] Similar norm-based scoring is currently used for the eight domain scales. The domain scores and PCS and MCS scores were estimated using standard US scoring algorithms.[11] The SF-36 has been widely validated for general population.[8,17–21] Further details on SF-36 are given elsewhere.[15,21]

Statistical analysis

All analyses in the present study were performed using SPSS software (version 26.0, IBM Corp., Armonk, NY). The descriptive statistics for the eight domains and two summary scores were calculated and reported. This included means, standard deviations (SD), 95% confidence intervals (CI), and percentage of floor (i.e., percentage of individuals with the lowest possible score on a scale) and ceiling (i.e., percentage of individuals with the highest possible score). Mean score imputation was implemented if at least 50% of the items in a scale were answered.[22]

The percentage of missing responses was evaluated at item level. A high percentage of missing data for a particular item may indicate problems with the wording used for that item. Another reason could be that respondents did not understand how to complete that part of the item.[23] Less than 10% of an item's missing data was deemed acceptable.[24]

Internal consistency reliability was assessed by determining Cronbach's alpha for each scale, PCS, and MCS with values of >0.4, >0.7, or >0.9 indicating satisfactory, good, or excellent internal consistency, respectively.[22,25,26]

Construct validity was evaluated using item convergent validity analyses, known groups comparisons, and convergent/divergent validity on scale level. Item convergent validity was assessed by examining the correlation between an item and the scale score computed from all other items in its scale (with correction for overlap). Item convergent validity was considered satisfactory if corrected item–scale correlations exceeded 0.4.[27] Known-groups validity was determined by investigating the associations between the SF-36 domains and population's demographics known to

Table 1
Characteristics of participants (n = 74,578).

	Number	Percent
Age category, years		
16–24	8368	11.2
25–34	8893	11.9
35–44	10,773	14.4
45–54	12,651	17.0
55–64	13,005	17.4
65–74	11,955	16.0
75+	8933	12.0
Sex		
Men	34,587	46.4
Women	39,991	53.6
BMI, kg/m^2		
Underweight (<18.5)	1367	1.8
Normal (18.5–24.9)	26,409	35.4
Overweight (25–30)	24,942	33.4
Obese (>30)	15,820	21.2
Highest level of education		
Degree or above	11,637	15.6
Other qualifications	43,533	58.4
No qualification	14,094	18.9
Employment status		
Currently employed	34,955	46.9
Not employed	36,347	48.7
Chronic illness		
Yes	38,671	51.9
No	34,547	46.3

Abbreviation: BMI, body mass index.

be related to health status such as age, gender, social class, limiting illness, hospitalisation in the last year, and attendance of accidents and emergency departments in the last three months.[17,18,28,29] Specifically we hypothesized that 1) scales concerning physical health (PF, RP, and BP) would show lower scores in older age groups, 2) persons in the age groups 45–54 years would have lower MH scores than younger and older age groups, 3) women would show lower scores than men on all scales, 4) persons in lower social classes would have lower scores of all scales, and 5) presence of limiting illness, hospitalisation, or hospital visits would be associated with lower scores on all scales.[22,30] Finally, construct validity was also examined using Pearson's correlation coefficient (r) to assess convergent and divergent validity among the domains of the SF-36. A value of $r \geq 0.70$ indicates a strong correlation; $0.30 < r < 0.70$ indicates a moderate correlation, and a value of $r \leq 0.30$ indicates a weak correlation.[31] For the assessment of convergent validity, we assumed a moderate to strong correlation within physical health-related domains (i.e., between PF, RP, BP, and GH scales) and within the mental health-related domains (i.e., between VT, SF, RE, and MH scales).[32] For the assessment of divergent validity, we assumed lower correlations across physical and mental domains than within physical or mental domains. Specifically, we examined correlations between PF and RE scales, between PF and MH scales, and between RP and MH scales.[31]

Results

Study sample

The characteristics of the sample are demonstrated in Table 1. This study included 74,578 participants aged 16 years or older. Approximately 17.4% of participants were 55–64 years old, and 53.6% were women, 35.4% had a normal weight, 58.4% had an education qualification lower than a tertiary degree, 48.7% were not employed, and 51.9% had a chronic illness.

Table 2
Internal consistency and item scale correlation.

Scale/item	Number	Mean	Standard deviation	Scale reliability[a]	Item scale correlation[b]
Physical functioning (10 items)	72,419	77.1	31.0	0.961	
1 Vigorous activities	67,546	2.1	0.8		0.661
2 Moderate activities	67,546	2.6	0.7		0.874
3 Lifting or carrying groceries	67,546	2.6	0.7		0.865
4 Climbing several flights of stairs	67,546	2.5	0.8		0.873
5 Climbing one flight of stairs	67,546	2.7	0.6		0.879
6 Bending, kneeling, stooping	67,546	2.5	0.7		0.823
7 Walk more than a mile	67,546	2.5	0.8		0.886
8 Walking several blocks	67,546	2.7	0.7		0.895
9 Walking one block	67,546	2.7	0.6		0.851
10 Bathing or dressing	67,546	2.8	0.5		0.745
Role-physical (4 items)	70,576	78.4	31.8	0.979	
1 Cut down time spent on work	69,505	4.2	1.3		0.935
2 Accomplished less than would like	69,505	4.1	1.3		0.944
3 Limited in kind of work/activities	69,505	4.2	1.3		0.956
4 Difficulty performing work/activities	69,505	4.1	1.3		0.950
Bodily pain (2 items)	73,436	69.5	28.6	0.772	
1 Intensity of bodily pain	72,614	2.5	1.7		0.669
2 Extent pain interfered with work	72,614	1.9	1.2		0.669
General health (5 items)	71,892	65.5	24.1	0.853	
1 Rating of general health	70,534	3.4	1.1		0.757
2 I seem to get sick easier than others	70,534	4.2	1.1		0.596
3 I seem as healthy as anyone I know	70,534	3.6	1.2		0.679
4 I expect my health to get worse	70,534	3.3	1.2		0.520
5 My health is excellent	70,534	3.4	1.3		0.801
Vitality (4 items)	72,594	56.4	22.8	0.844	
1 Full of life	70,727	2.7	1.1		0.686
2 Have a lot of energy	70,727	2.9	1.2		0.700
3 Feel worn out	70,727	2.5	1.1		0.656
4 Feel tired	70,727	2.9	1.0		0.679
Social functioning (2 items)	73,451	79.5	28.6	0.887	
1 Extent health problems interfered	72,159	4.2	1.2		0.797
2 Frequency health problems interfered	72,159	4.2	1.2		0.797
Role-emotional (3 items)	70,176	86.8	26.0	0.969	
1 Cut down time spent on work	69,727	4.5	1.1		0.941
2 Accomplished less than would like	69,727	4.4	1.1		0.940
3 Work not done as carefully as usual	69,727	4.5	1.0		0.923
Mental health (5 items)	72,341	73.5	19.7	0.845	
1 Been a very nervous person	70,314	4.3	1.0		0.599
2 Feel down in the dumps	70,314	4.3	1.0		0.738
3 Felt calm and peaceful	70,314	3.3	1.1		0.583
4 Felt downhearted and blue	70,314	4.1	1.0		0.721
5 Been a happy person	70,314	3.7	0.9		0.626
PCS	67,770	47.0	12.0	0.960	
MCS	67,770	50.7	9.9	0.934	

Abbreviations: MCS, mental component summary; PCS, physical component summary.
[a] Internal consistency reliability.
[b] Correlations between items and own scale, corrected for overlap (higher correlations indicate good internal consistency).

Table 3
Mean scores for the SF-36 domains by age, sex, social class, and health variables.

Variable	Physical functioning (0–100 metric)			Role physical (0–100 metric)			Bodily pain (0–100 metric)			General health (0–100 metric)		
	n	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
Age, years												
16–24	8222	92.4	19.3	8150	93.8	17.0	8257	85.1	20.4	8185	75.3	20.4
25–34	8760	91.0	20.3	8684	90.6	21.6	8783	79.9	23.9	8732	72.1	20.8
35–44	10,610	88.2	22.8	10,490	88.1	24.6	10,665	75.7	25.9	10,567	70.3	21.9
45–54	12,376	82.6	26.8	12,226	82.9	29.5	12,506	69.6	28.2	12,357	65.7	24.3
55–64	12,682	73.5	31.2	12,394	74.9	33.2	12,844	64.1	29.2	12,622	61.7	25.0
65–74	11,464	64.9	32.9	10,956	66.7	34.3	11,742	61.1	29.0	11,362	60.4	24.7
75+	8305	46.9	33.2	7676	50.3	34.8	8639	55.8	29.2	8067	54.9	23.7
Sex												
Men	33,621	79.8	29.9	32,928	79.9	31.3	34,077	71.9	27.9	33,424	66.4	23.9
Women	38,798	74.7	31.8	37,648	77.1	32.2	39,359	67.4	29.0	38,468	64.7	24.2
Social class [a]												
1	26,522	82.4	26.8	26,187	83.0	28.3	26,666	73.4	26.1	26,430	69.4	22.1
2	5119	76.8	30.8	5008	78.2	31.9	5151	69.6	28.4	5074	65.1	23.7
3	8878	78.3	30.1	8666	79.0	30.9	9051	70.2	28.2	8821	67.6	23.2
4	9679	73.7	33.0	9384	75.6	33.5	9863	66.8	29.5	9615	63.4	24.8
5	18,539	70.8	34.3	17,754	73.0	35.0	18,981	64.8	30.6	18,331	60.6	25.6
6	1686	65.3	36.1	1585	67.9	36.1	1712	63.0	31.7	1633	54.5	25.8
Limiting illness												
Yes	25,419	50.1	32.8	24,232	48.8	34.1	25,994	45.2	26.1	25,136	45.7	23.0
No	46,046	92.2	16.2	45,669	94.3	14.6	46,584	83.1	19.3	46,123	76.4	16.6
Inpatient [b]												
Yes	6651	57.1	37.0	6358	54.2	39.0	6770	51.7	31.2	6540	50.7	26.8
No	65,266	79.2	29.5	63,780	80.9	29.9	66,133	71.4	27.6	64,878	67.0	23.3
Attended A&E [c]												
Yes	3089	70.8	34.7	2973	67.7	37.0	3136	56.8	31.2	3050	59.8	26.4
No	69,089	77.4	30.7	67,397	79.0	31.4	70,012	70.1	28.3	68,622	65.8	23.9

Variable	Vitality (0–100 metric)			Social functioning (0–100 metric)			Role emotional (0–100 metric)			Mental health (0–100 metric)		
	n	Mean	SD	*n*	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
Age, years												
16–24	8192	65.0	21.1	8266	88.1	21.3	8135	92.2	19.1	8187	75.2	18.9
25–34	8738	58.3	20.8	8795	84.7	24.2	8666	90.2	21.8	8733	72.9	19.3
35–44	10,606	57.0	21.5	10,672	83.4	25.8	10,481	89.6	23.0	10,606	72.5	19.7
45–54	12,431	55.5	22.7	12,512	80.3	28.7	12,192	87.9	25.3	12,413	71.6	20.9
55–64	12,747	55.5	23.3	12,847	77.7	30.0	12,361	85.7	27.3	12,715	72.9	20.4
65–74	11,558	56.1	23.4	11,739	76.6	30.0	10,844	84.1	28.1	11,495	75.9	19.1
75+	8322	48.5	23.1	8620	67.1	32.6	7497	77.2	32.4	8192	74.4	18.8
Sex												
Men	33,662	59.9	22.3	34,101	82.1	27.5	32,769	88.6	24.9	33,572	76.0	19.1
Women	38,932	53.4	22.7	39,350	77.3	29.3	37,407	85.2	26.8	38,769	71.4	20.1
Social class [a]												
1	26,544	59.3	21.2	26,689	84.1	25.4	26,119	90.7	21.3	26,513	76.4	17.6
2	5107	54.3	23.0	5150	78.8	29.0	5010	86.7	25.5	5095	72.7	19.9
3	8909	58.6	22.1	9042	82.0	27.1	8641	88.6	24.2	8877	76.0	18.6
4	9733	55.7	23.0	9869	77.8	29.5	9283	85.4	27.2	9683	73.3	19.8
5	18,633	52.7	24.2	18,973	74.0	31.3	17,581	81.9	30.4	18,516	69.7	21.7
6	1672	49.3	24.5	1711	66.1	33.5	1566	74.1	34.6	1660	63.5	23.9
Limiting illness												
Yes	25,595	41.2	21.9	26,010	57.9	32.1	23,885	71.1	34.6	25,402	64.7	22.2
No	46,271	64.9	18.4	46,607	91.7	17.0	45,673	95.1	14.1	46,234	78.4	16.3
Inpatient [b]												
Yes	6657	43.8	23.9	6781	59.2	34.6	6248	74.1	35.2	6608	66.1	22.3
No	65,433	57.7	22.2	66,141	81.7	27.0	63,502	88.1	24.5	65,237	74.3	19.3
Attended A&E [c]												
Yes	3084	51.6	24.5	3139	67.9	33.5	2960	79.6	32.2	3070	67.8	22.7
No	69,254	56.7	22.6	70,026	80.1	28.2	67,037	87.2	25.5	69,032	73.8	19.5

Variable	PCS			MCS		
	n	Mean	SD	*n*	Mean	SD
Age, years						
16–24	7945	55.2	6.8	7945	50.3	10.7
25–34	8491	53.9	8.1	8491	48.6	11.2
35–44	10,254	52.4	9.3	10,254	48.7	11.2
45–54	11,879	49.7	11.0	11,879	48.8	11.6
55–64	11,963	46.0	12.5	11,963	49.9	11.4
65–74	10,339	42.7	13.1	10,339	51.8	10.9
75+	6899	36.6	13.0	6899	50.7	11.5

Table 3 (*continued*)

Variable	PCS			MCS		
	n	Mean	SD	*n*	Mean	SD
Sex						
Men	31,702	48.9	11.9	31,702	51.1	10.7
Women	36,068	47.7	12.6	36,068	48.6	11.7
Social class [a]						
1	25,575	49.9	11.2	25,575	51.2	10.0
2	4865	48.0	12.6	4865	49.1	11.7
3	8274	48.4	12.0	8274	51.1	10.5
4	8947	46.9	12.9	8947	49.8	11.3
5	16,748	46.2	13.2	16,748	47.8	12.5
6	1452	45.1	13.5	1452	44.2	14.6
Limiting illness						
Yes	22,753	36.1	12.3	22,753	45.0	14.0
No	44,558	54.5	6.1	44,558	52.2	8.7
Inpatient [b]						
Yes	5961	39.3	14.6	5961	45.3	13.7
No	61,433	49.1	11.7	61,433	50.2	10.9
Attended A&E [c]						
Yes	2846	44.7	13.5	2846	46.6	13.6
No	64,776	48.4	12.2	64,776	49.9	11.2

Abbreviations: MCS, mental component summary; *n*, number; PCS, physical component summary; SD, standard deviation.
[a] National Statistics Socio-economic Classification (NS-SEC): 1, managerial or professional occupations; 2, intermediate occupations; 3, small employers own account workers; 4, lower supervisory and technical occupations; 5, semi-routine and routine occupations; 6, never worked and long-term unemployed.
[b] Being inpatient in the last 12 months.
[c] Attended accidents and emergency departments in the last 3 months.

The rates of missing items for the SF-36 domains and component summaries are demonstrated in Appendix Table 1. For all domains, the highest rates were found for those aged ≥75 years, and, except for VT, rates were always higher in women than men. The highest total rates of missing items were reported for RE (5.9%), RP (5.3%), GH (3.6%), and MH (3.0%).

Internal consistency reliability

A good to excellent internal consistency reliability was demonstrated for all domains (Table 2). In particular, the highest values were demonstrated for RP (0.979), RE (0.969), and PF (0.961). Both PCS and MCS achieved excellent internal consistency reliability with a Cronbach's alpha of 0.960 and 0.934, respectively. Overall, the results suggest high reliability for the eight scales and for PCS and MCS.

Construct validity

All corrected item–scale correlations exceeded 0.4 (Table 2), thus supporting item convergent validity. The data regarding the relationship between the SF-36 domains and various variables known to be associated with health were shown in Table 3. In general, worse health status (representing lower mean scores on SF-36 domains) has been shown to be related to older ages, being a woman and belonging to a lower socio-economic class. Furthermore, those who had a limiting illness, had been inpatient in hospital in the last 12 months and had attended emergency departments in the last 3 months, have been shown to have a worse health status.

The results concerning convergent and divergent validity among the SF-36 domains were shown in Table 4. For the assessment of the convergent validity, moderate to strong correlations were demonstrated among the four physical health-related domains (r = 0.647–0.799); moderate to strong correlations were also demonstrated among the four mental health-related domains (r = 0.537–0.700). For the assessment of the divergent validity, lower correlations were demonstrated across domains than within domains: between PF and RE (r = 0.527), between PF and MH (r = 0.355), and between RP and MH (r = 0.414).

Normative data

The normative data of the SF-36 domains and component summaries, PCS and MCS, for the different age groups are presented in Tables 5 (for the total population), 6 (for men), and 7 (for women) and Appendix Tables 2–4, respectively. Participants aged 16–24 years scored higher than older groups on all domains. Generally, the SF-36 profiles by age group demonstrated lower scores for older age groups, with the most pronounced differences shown on the physical-related scales. Across the age groups, men scored higher than women on all domains, except for those aged 55–64 and 65–74 years, whereas women ($\Delta_{GH} = 45.7$ and $\Delta_{GH} = 45.2$; 0–100 metric) scored higher than men ($\Delta_{GH} = 45.6$ and $\Delta_{GH} = 44.8$),

Table 4
Correlations between SF-36 domains (Pearson's r).

	Physical functioning	Role physical	Bodily pain	General health	Vitality	Social functioning	Role emotional	Mental health
Physical functioning	–							
Role physical	0.799	–						
Bodily pain	0.662	0.719	–					
General health	0.647	0.678	0.654	–				
Vitality	0.541	0.596	0.594	0.695	–			
Social functioning	0.641	0.737	0.652	0.676	0.676	–		
Role emotional	0.527	0.629	0.488	0.541	0.537	0.700	–	
Mental health	0.355	0.414	0.426	0.548	0.683	0.647	0.613	–

Table 5
Mean SF-36 scores for Welsh adults – stratified by age.

Age in years	Physical functioning (NBS)	Role physical (NBS)	Bodily pain (NBS)	General health (NBS)	Vitality (NBS)	Social functioning (NBS)	Role emotional (NBS)	Mental health (NBS)	PCS	MCS
16-24										
n	8222	8150	8257	8185	8192	8266	8135	8187	7945	7945
Mean	53.9	54.4	55.8	52.1	53.3	51.7	52.2	50.1	53.9	50.9
SD	8.1	6.7	8.6	9.7	10.5	9.3	8.9	10.6	6.7	9.6
95% CI	53.7–54.0	54.3–54.6	55.6–56.0	51.9–52.3	53.1–53.5	51.5–51.9	52.0–52.4	49.9–50.4	53.7–54.0	50.7–51.1
25-34										
n	8760	8684	8783	8732	8738	8795	8666	8733	8491	8491
Mean	53.3	53.2	53.6	50.6	50.0	50.2	51.3	48.8	52.5	49.3
SD	8.6	8.4	10.1	9.9	10.4	10.6	10.1	10.9	7.9	10.0
95% CI	53.1–53.4	53.0–53.4	53.4–53.8	50.4–50.8	49.8–50.2	49.9–50.4	51.1–51.5	48.6–49.0	52.3–52.7	49.1–49.6
35-44										
n	10,610	10,490	10,665	10,567	10,606	10,672	10,481	10,606	10,254	10,254
Mean	52.0	52.2	51.9	49.7	49.3	49.6	51.0	48.6	51.1	49.5
SD	9.6	9.6	10.9	10.4	10.7	11.3	10.7	11.1	9.1	10.0
95% CI	51.9–52.2	52.0–52.4	51.6–52.1	49.5–49.9	49.1–49.6	49.4–49.8	50.8–51.2	48.4–48.8	50.9–51.3	49.3–49.7
45-54										
n	12,376	12,226	12,506	12,357	12,431	12,512	12,192	12,413	11,879	11,879
Mean	49.7	50.2	49.3	47.6	48.6	48.2	50.2	48.1	48.4	49.6
SD	11.3	11.6	11.9	11.6	11.4	12.5	11.8	11.7	10.9	10.2
95% CI	49.5–49.9	50.0–50.4	49.1–49.5	47.4–47.8	48.4–48.8	48.0–48.5	50.0–50.4	47.9–48.3	48.2–48.6	49.4–49.8
55-64										
n	12,682	12,394	12,844	12,622	12,747	12,847	12,361	12,715	11,963	11,963
Mean	45.9	47.0	47.0	45.7	48.6	47.1	49.2	48.8	44.9	50.8
SD	13.1	13.0	12.3	11.9	11.7	13.1	12.7	11.5	12.3	9.9
95% CI	45.7–46.1	46.8–47.3	46.7–47.2	45.4–45.9	48.4–48.8	46.9–47.3	49.0–49.4	48.6–49.0	44.7–45.1	50.7–51.0
65-74										
n	11,464	10,956	11,742	11,362	11,558	11,739	10,844	11,495	10,339	10,339
Mean	42.3	43.8	45.7	45.0	48.9	46.6	48.5	50.5	41.7	52.7
SD	13.8	13.4	12.3	11.8	11.7	13.1	13.1	10.8	12.8	9.3
95% CI	42.0–42.5	43.6–44.1	45.4–45.9	44.8–45.2	48.7–49.1	46.4–46.9	48.2–48.7	50.3–50.7	41.5–42.0	52.6–52.9
75+										
n	8305	7676	8639	8067	8322	8620	7497	8192	6899	6899
Mean	34.7	37.4	43.4	42.4	45.1	42.5	45.2	49.7	35.8	52.0
SD	14.0	13.6	12.3	11.3	11.5	14.2	15.1	10.6	12.6	9.8
95% CI	34.4–35.0	37.1–37.7	43.2–43.7	42.2–42.6	44.9–45.4	42.2–42.8	44.9–45.6	49.4–49.9	35.5–36.1	51.8–52.3

Abbreviations: CI, confidence interval; *n*, number; NBS, norm-based score; MCS, mental component summary; PCS, physical component summary; SD, standard deviation.

respectively, on GH. Men aged 16–24 years had higher scores than women aged 16–24 years on all domains (score differences: $\Delta_{PF} = 1.4$, $\Delta_{RP} = 0.8$, $\Delta_{BP} = 2.3$, $\Delta_{GH} = 3.7$, $\Delta_{VT} = 4.8$, $\Delta_{SF} = 2.4$, $\Delta_{RE} = 1.8$, and $\Delta_{MH} = 3.2$).

For men, mean scores decreased gradually with advancing age on PF, RP, BP, GH, SF, and RE. Furthermore, men aged 16–24 years had a 54.6, 54.8, 57.0, 54.1, 55.8, 52.9, 53.2, and 51.8 points higher score than those aged ≥75 years on PF, RP, BP, GH, VT, SF, RE, and MH, respectively (0–100 metric). However, on the MH domain, it has been found that those aged 16–24 years had the highest score followed by those aged 65–74 years and then those aged ≥75 years across the age groups.

Women followed a similar trend as men, although generally with slightly lower scores. The mean scores decreased gradually with advancing age on the PF, RP, BP, GH, VT, SF, RE, and MH domains. Furthermore, women aged 16–24 years had a 53.2, 54.0, 54.7, 50.4, 51.0, 50.5, and 51.4 points higher than those aged ≥75 years on PF, RP, BP, GH, VT, SF, and RE domains, respectively. On the MH domain, however, women aged 65–74 years had the highest score followed by women aged ≥75 years and then those aged 16–24 years across the age groups.

Across the age groups, men had higher PCS and MCS scores than women. Younger age groups achieved higher scores, which decreased gradually with advancing age. However, for MCS, both men and women aged 65–74 years achieved the highest score across age groups. The highest second group among men was those aged ≥75 years followed by those aged 16–24 years. Furthermore, the highest second group among women was those aged ≥75 years followed by those aged 55–64 years.

Discussion

Health-related quality of life entails the subjective evaluation of one's physical, psychological, social status, and other facets of health. As HRQoL is a multidimensional construct, it includes complex and diversified facets of physical, psychological, and social health.[1–3] It stems from subjective reports of functioning and well-being in these different domains of life. Functioning regards mainly physical, role, and social functioning. Well-being encompasses positive and negative emotions, as well as symptoms such as fatigue and pain.[4,5] Thus, HRQoL is an important indicator of health, which can provide insights on well-being and functional health of

Table 6
Mean SF-36 scores for Welsh men – stratified by age.

Age in years	Physical functioning (NBS)	Role physical (NBS)	Bodily pain (NBS)	General health (NBS)	Vitality (NBS)	Social functioning (NBS)	Role emotional (NBS)	Mental health (NBS)	PCS	MCS
16-24										
n	3933	3903	3945	3894	3900	3952	3897	3900	3796	3796
Mean	54.6	54.8	57.0	54.1	55.8	52.9	53.2	51.8	54.8	52.5
SD	7.4	6.2	7.8	9.0	9.9	8.3	8.0	10.1	6.0	8.9
95% CI	54.4–54.8	54.6–55.0	56.8–57.3	53.8–54.3	55.5–56.1	52.7–53.2	52.9–53.4	51.4–52.1	54.6–55.0	52.2–52.8
25-34										
n	3842	3816	3855	3824	3828	3862	3806	3826	3723	3723
Mean	53.7	53.6	54.5	51.4	52.3	51.4	52.3	50.5	52.9	51.0
SD	8.4	8.2	9.7	9.8	10.2	9.8	9.4	10.6	7.5	9.4
95% CI	53.5–54.0	53.4–53.9	54.1–54.8	51.1–51.7	52.0–52.7	51.1–51.7	52.0–52.6	50.1–50.8	52.6–53.1	50.7–51.3
35-44										
n	4857	4823	4887	4834	4843	4892	4812	4846	4698	4698
Mean	52.8	52.9	52.7	50.3	51.4	50.9	51.9	50.0	51.6	50.9
SD	9.2	9.1	10.4	9.9	10.2	10.5	10.1	10.8	8.3	9.5
95% CI	52.5–53.0	52.6–53.1	52.4–53.0	50.1–50.6	51.2–51.7	50.6–51.2	51.6–52.2	49.7–50.3	51.3–51.8	50.6–51.2
45-54										
n	5753	5716	5820	5754	5783	5822	5702	5777	5560	5560
Mean	50.9	51.0	50.4	48.0	50.4	49.8	51.2	49.6	49.2	50.9
SD	10.6	11.0	11.5	11.3	11.0	11.7	11.0	11.3	10.2	9.6
95% CI	50.6–51.2	50.7–51.3	50.1–50.7	47.7–48.2	50.2–50.7	49.5–50.1	50.9–51.5	49.3–49.9	48.9–49.4	50.7–51.2
55-64										
n	6020	5897	6096	5998	6046	6100	5889	6028	5709	5709
Mean	47.0	47.6	47.7	45.6	49.8	48.1	50.1	50.0	45.5	51.8
SD	12.9	12.9	12.2	11.8	11.4	12.8	12.3	11.1	11.9	9.4
95% CI	46.7–47.4	47.3–48.0	47.4–48.0	45.3–45.9	49.5–50.1	47.7–48.4	49.7–50.4	49.7–50.3	45.2–45.8	51.5–52.0
65-74										
n	5510	5310	5625	5490	5554	5628	5258	5534	5052	5052
Mean	43.6	44.3	46.8	44.8	50.0	47.3	49.2	51.7	42.4	53.4
SD	13.7	13.5	12.1	11.7	11.6	12.9	12.8	10.5	12.6	9.0
95% CI	43.3–44.0	44.0–44.7	46.4–47.1	44.5–45.1	49.7–50.3	47.0–47.6	48.8–49.5	51.4–51.9	42.1–42.8	53.2–53.7
75+										
n	3706	3463	3849	3630	3708	3845	3405	3706	3164	3164
Mean	37.1	38.1	44.8	42.7	46.5	43.4	45.9	50.9	37.3	52.7
SD	14.1	13.7	12.3	11.3	11.5	14.1	14.9	10.1	12.8	9.3
95% CI	36.6–37.5	37.6–38.5	44.4–45.2	42.3–43.0	46.1–46.9	43.0–43.8	45.4–46.4	50.5–51.2	36.9–37.7	52.3–53.0

Abbreviations: CI, confidence interval; *n*, number; NBS, norm-based score; MCS, mental component summary; PCS, physical component summary; SD, standard deviation.

the general population. It can also offer additional information about individuals who are suffering from disorders/diseases. HRQoL is generally assessed through self-report questionnaires.

The SF-36 is one of the most extensively used generic instruments for measuring HRQoL worldwide,[33–35] assessing PF, RP, BP, GH, VT, SF, RE, and MH. These eight domains can be combined to calculate global measures of physical and mental health, the PCS and the MCS.[15]

The availability of normative data for the SF-36 measure from a representative sample of the population is pivotal in order to interpret findings from specific populations. Indeed, normative data for the SF-36 are available for several peoples and languages[1,2,6,7,36–41] showing differences and similarities among studies regarding collection of data, samples' characteristics, and statistical analysis. For Wales (UK), the latest available data providing norms for the SF-36 date back 15 years,[8] thus they could be no longer representative for the current population. Moreover, HRQoL is a dynamic construct, prone to variations over time, according to the individual's priorities, goals, and expectations, which are likely to change over different phases of life. Therefore, up-to-date data gathered from a large, stratified sample may shed light on the quality of life of individuals currently living in a specific area or country, and to identify normative data for this specific population.

The aims of this study were to obtain population normative data for the SF-36 and to evaluate its reliability and construct validity for the Welsh, using population-based data from the WHS. Our results show that, for all domains, the highest rates of missing items were found for those aged ≥75 years, confirming previous data on the same population,[8] and, except for the scale VT, rates of missing were higher in women than men. The highest total rates of missing items were reported for RP, RE, GH, and MH. However, the missing data for all domains in this study was deemed acceptable (<10%). This might be as a result of the mode of data administration, which used face-to-face interview with participants in their household. The mode of data administration might have an impact on data quality; for example, the missing items were reported to be higher in postal survey compared to face-to-face interview method, and in postal survey compared to telephone interview.[42]

Our results also show very good internal consistency reliability for all domains, with Cronbach's alphas ranging from good to excellent, confirming the results of previous research on the Welsh population[8] and supporting the SF-36 as a reliable instrument. In particular, the highest values were obtained for RP, RE, and PF.

The construct validity of the SF-36 scales and of the summary measures was assessed using the 'known-groups' technique, which

Table 7
Mean SF-36 scores for Welsh women – stratified by age.

Age in years	Physical functioning (NBS)	Role physical (NBS)	Bodily pain (NBS)	General health (NBS)	Vitality (NBS)	Social functioning (NBS)	Role emotional (NBS)	Mental health (NBS)	PCS	MCS
16-24										
n	4289	4247	4312	4291	4292	4314	4238	4287	4149	4149
Mean	53.2	54.0	54.7	50.4	51.0	50.5	51.4	48.6	53.0	49.4
SD	8.7	7.0	9.2	10.0	10.5	50.2	9.6	10.9	7.2	10.1
95% CI	52.9–53.4	53.8–54.2	54.4–55.0	50.1–50.7	50.7–51.3	50.2–50.8	51.1–51.7	48.3–49.0	52.8 –53.2	49.1 –49.7
25-34										
n	4918	4868	4928	4908	4910	4933	4860	4907	4768	4768
Mean	52.9	52.8	53.0	50.0	48.1	49.2	50.6	47.5	52.3	48.0
SD	8.7	8.7	10.3	9.9	10.2	11.0	10.7	11.0	8.2	10.2
95% CI	52.6–53.1	52.6–53.1	52.7–53.3	49.7–50.3	47.8–48.4	48.9–49.5	50.3–50.9	47.2–47.8	52.1 –52.5	47.8 –48.3
35-44										
n	5753	5667	5778	5733	5763	5780	5669	5760	5556	5556
Mean	51.4	51.6	51.1	49.2	47.6	48.5	50.3	47.4	50.7	48.3
SD	9.9	10.0	11.4	10.8	10.8	11.7	11.2	11.2	9.7	10.2
95% CI	51.2–51.7	51.4–51.9	50.9–51.4	49.0–49.5	47.3–47.9	48.2–48.8	50.0–50.6	47.1–47.7	50.4 –50.9	48.1 –48.6
45-54										
n	6623	6510	6686	6603	6648	6690	6490	6636	6319	6319
Mean	48.7	49.4	48.3	47.2	47.0	46.9	49.4	46.8	47.8	48.4
SD	11.7	12.0	12.1	11.9	11.4	13.0	12.4	12.0	11.4	10.6
95% CI	48.4–49.0	49.1–49.7	48.0–48.6	46.9–47.5	46.7–47.3	46.6–47.2	49.1–49.7	46.5–47.1	47.5 –48.1	48.2 –48.7
55-64										
n	6662	6497	6748	6624	6701	6747	6472	6687	6254	6254
Mean	44.9	46.5	46.3	45.7	47.5	46.3	48.4	47.8	44.3	50.0
SD	13.3	13.1	12.4	12.1	11.8	13.3	13.1	11.7	12.5	10.3
95% CI	44.5–45.2	46.2–46.8	46.0–46.5	45.4–46.0	47.3–47.8	46.0–46.6	48.1–48.8	47.5–48.1	44.0 –44.6	49.8 –50.3
65-74										
n	5954	5646	6117	5872	6004	6111	5586	5961	5287	5287
Mean	41.0	43.3	44.7	45.2	47.9	46.0	47.8	49.4	41.0	52.1
SD	13.8	13.3	12.3	11.8	11.7	13.2	13.3	10.9	12.9	9.6
95% CI	40.6–41.3	43.0–43.7	44.4–45.0	44.9–45.5	47.6–48.2	45.7–46.3	47.5–48.2	49.2–49.7	40.7 –41.4	51.8 –52.3
75+										
n	4599	4213	4790	4437	4614	4775	4092	4531	3735	3735
Mean	32.8	36.8	42.3	42.2	44.0	41.8	44.7	48.7	34.5	51.5
SD	13.6	13.5	12.2	11.3	11.4	14.3	15.3	10.8	12.4	10.1
95% CI	32.4–33.2	36.4–37.2	42.0–42.6	41.9–42.5	43.7–44.3	41.4–42.2	44.3–45.2	48.4–49.0	34.1 –34.9	51.2 –51.8

Abbreviations: CI, confidence interval; *n*, number; NBS, norm-based score; MCS, mental component summary; PCS, physical component summary; SD, standard deviation.

evaluates differences in SF-36 scores between subgroups of individuals classified by attributes hypothesized to predict quality of life related to health. Our findings on the associations between the SF-36 domains and a range of dimensions typically related to health, such as gender, age, social class, limiting illness, hospitalisation in the previous year, and attendance at emergency departments, supported the construct validity of the SF-36. Our findings support the use of this questionnaire as an appropriate instrument to measure HRQoL, as shown in previous studies.[1,2,6,7,36–41]

Construct validity was also examined by assessing convergent and divergent validity among the eight domains of the SF-36. In terms of convergent validity, moderate to strong correlations were shown among the four physical health-related domains and also among the four mental health-related domains. This finding indicates that these domains had sufficient convergent validity. In terms of divergent validity, the correlations were moderate between PF and RE, between PF and MH, and between RP and MH; indicating that these domains are distinct from each other.

The findings of this study show that worse health status, as measured by the SF-36, was associated with older age, being a woman, and belonging to a lower socio-economic class. Across the various age groups, men scored higher than women on all domains, except for the 65–74 years age range, where women scored higher than men on general health. Men aged 16–24 years had higher scores than women aged 16–24 years on all domains, a finding in line with previous studies indicating that self-reported complaints increase with age and are more prevalent among women than men.[43] This may be due to several sociocultural factors: first, women have less wealth than men in almost all societies, and even if they pursue a career, they have significantly lower income than men,[44] but at the same time they have higher burdens of work.[45] Thus, a cycle of low income, and worse health are set in motion.[44] Furthermore, studies on sex differences in health, disability, and physical functioning show that women have worse physical functioning and report more disability than men.[46]

Worse health status (as measured by the SF-36) was related to older ages, with participants aged 16–24 years scoring higher than older groups on all domains. Generally, the SF-36 profiles by age group demonstrated lower scores for older age groups, with the most pronounced differences shown on the physical-related scales. Mean scores decreased gradually with advancing age, a finding in line with previous research.[36–41,47,48]

The present study includes a very large sample of 74,578 individuals, drawing from population-based data collected through multistage, stratified probability sampling from the WHS (2011–2015). The survey is based on a representative sample of

people living in private households in Wales. This sampling strategy allows us to measure the health and lifestyle of a cross-section of the population, not just those who are affected by physical/mental illnesses or have regular contact with health services, thus shedding light on the quality of life of a diverse population. Nevertheless, the WHS sampling method has a few limitations, first because it only includes private households while excludes institutions such as care homes: individuals whose level of health was presumably very low and that lived in institutions could not be included in the picture, thus generating a bias that should be taken into account when interpreting the results. Indeed, the results reflect individuals' own understanding of their health rather than being an objective assessment of their physical/mental condition made by a professional. At the same time, this could also be a strength, given that HRQoL concerns the individuals' subjective perception of the impact that illness/disability and treatments have on their life, and that such a personal perspective may be more easily conveyed by a self-report method than talking to a stranger.

Our findings indicate that HRQoL in Wales follows a similar pattern as in other countries, with overall better HRQoL in men compared to women; regarding age, older individuals report a worse physical and better mental health.[36–41,47,48]

In summary, the present study provides national estimates of HRQoL in Wales; identifies population sub-groups according to age, gender, and so on; confirms the construct validity and reliability of the SF-36; and provides data that can inform policies aimed at promoting an enhanced quality of life. The updated normative data resulting from this study should be used in future research with the Welsh population, not only for cross-sectional and longitudinal studies, but also for experimental studies on the effectiveness of interventions aimed at increasing well-being, and in cross-cultural research on HRQoL.

Author statements

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Ethical approval

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Competing interests

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.

Author contributions

HA and YSA: substantial contribution to the conception and design of the study. HA and YSA: substantial contributions to the acquisition and substantial contributions to analysis or interpretation of data. HA, YSA, BB, MAA, MA, and JB: drafting the work. All authors revised the work critically for important intellectual content and provided approval for publication of the content. All authors contributed to the article and approved the submitted version.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.11.010.

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Review Paper

Impact of COVID-19 lockdown on smoking and vaping: systematic review and meta-analysis

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ABSTRACT

Objectives: COVID-19 and the implementation of lockdowns have impacted daily lives worldwide. This systematic review and meta-analysis aimed to investigate the impact of lockdowns on the smoking and vaping behaviours of adults during the pandemic.
Study design: This was a systematic review and meta-analysis.
Methods: A systematic literature search was conducted up to 28 April 2022 in the following databases: PubMed, Embase and Web of Science.
Results: In total, 77 studies met the inclusion criteria for this review. In 34 studies, an increase in smoking behaviour was reported for the majority of participants; however, in 21 and 18 studies, 'no change' and 'decrease' in smoking were the predominant responses, respectively. The results from the meta-analysis, which examined the change in the number of cigarettes smoked per day, showed no difference between the pre- and post-lockdown periods: 0.81 weighted mean difference (95% confidence interval, −0.59 to 2.21). Regarding vaping, three of seven studies reported an increase in smoking for the majority of participants, whereas 'no change' and 'decrease' were the predominant answers in the other four studies.
Conclusions: The results show that lockdowns led most participants to increase smoking/vaping, whereas a decrease or cessation of smoking/vaping was only reported in the minority of participants. Attention should be given to the non-communicable diseases that could arise as a result of the increase in smoking/vaping during lockdowns, and further research in this area is needed.

Introduction

The novel COVID-19 was initially detected in Wuhan, China, near the end of 2019. On 11 March 2020, a pandemic was declared by the World Health Organization.[1] COVID-19 spread quickly because of its extended incubation period and highly infectious characteristics, as well as significant worldwide networking and significant global travel activities.[2] By April 2022, COVID-19 had infected over 300 million individuals and resulted in over 6.2 million deaths.[3] Although the global response to COVID-19 has been far from uniform, most countries have implemented self-isolation, homestay (or lockdown) requirements, social distancing or quarantine measures to reduce COVID-19 transmission and ease the burden on healthcare services until the vaccine became available; however, lockdowns also led to unexpectedly serious health repercussions.[4] Even after the approval and distribution of the vaccines, several countries continued to impose lockdowns when they deemed it essential; these lockdowns have impacted the everyday lives of many people and constituted a severe threat to individuals with addictive behaviours.[5] Evidence on the risk of contracting COVID-19 based on smoking status remains inadequate and conflicting, underlining the need to increase quantitative research with more rigorous study designs.[6–8] Smoking appears to be connected to higher COVID-19 hospitalisation and mortality, even if the linkage for current smokers is still ambiguous.[6,9,10]

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COVID-19 preventive approaches, such as social distancing and stay-at-home mandates, had a significant impact on interpersonal dynamics.[11,12] Many people were confined to their homes during lockdown periods, either alone, with family members or with other housemates, in addition to participating in fewer social and physical activities.[13–15] These modifications might be especially important for those who smoke in public places or who live with children or other vulnerable people.[16] Pandemic-related issues might also induce increased stress, which is known to lead to increased smoking on an individual basis.[17,18] Notably, after disasters or traumatic events in the United States, such as the September 11th terrorist attacks and Hurricane Katrina, smoking behaviours increased.[19] On the other hand, for some people, a respiratory illness epidemic (such as COVID-19) could be regarded as an ideal moment to decrease or quit smoking because of health concerns.[20] As a result, smoking behaviours could differ from pre-COVID-19 routines in terms of where, when and with whom people smoke; however, the results of current quantitative studies investigating the COVID-19 effects on smoking have shown conflicting results.[21–25]

It is therefore essential that data from existing quantitative research on the influence of COVID-19 on smoking and/or vaping behaviours are collected and analysed to get a more accurate conclusion of the impact of the pandemic on smoking and vaping habits. This study attempted to present an overview of the current data regarding the impact of COVID-19 lockdowns on smoking and vaping behaviours.

Methods

Search strategy and study selection

A systematic literature search was conducted in PubMed, Web of Science and Embase databases up to 28 April 2022. A combination of the key terms ((smoking) OR (tobacco) OR (vaping) OR (cigarette) OR (lifestyle)) AND ((Covid-19) OR (Covid) OR (Covid-19) OR (Sars-cov-2) OR (lockdown)) was used as a search string for PubMed and was modified accordingly for the other databases. The search strategy of this study can be found in Supplementary File S1. The studies identified through the literature search were added into reference manager software (Endnote X9; Thomson Reuters, for Windows) and were screened independently for eligibility by two reviewers (D.B. and K.E.). Any disagreement was solved by consensus. Reference lists of the eligible studies were also screened for additional relevant studies.

The present study was conducted according to the registered protocol in the OSF platform (https://osf.io/vj586/). Eligible studies were observational studies (prospective, retrospective cohort studies and cross-sectional studies) that examined the change in smoking and/or vaping behaviour of adults during the COVID-19 lockdowns. Retrospective studies that were started before the COVID-19 lockdowns were excluded to avoid any other confounding factors. Moreover, studies in which there was a statement that the results referred to combined smoking and vaping change were excluded. Studies that included children (aged <18 years) as a population of interest were also excluded. Editorials, letters to the editor, reviews and studies in languages other than English, French or Spanish were not included in this review.

Data extraction

Information from eligible studies was extracted independently by two authors (D.B. and K.E.) using a standardised data extraction form. Any discrepancies were resolved by consultation with a third author (M.C.) who was not involved in the initial procedure. Study identity (first author, year of publication), country of origin, sex, age and subgroups of participants (if applicable), period when the survey was conducted and information regarding smoking and/or vaping habit before and during/after the COVID-19 lockdown periods were recorded. Specifically, increase, decrease, no change, as well as initiation and cessation of smoking and/or vaping behaviour as a result of COVID-19 restriction measures were examined. Corresponding authors of articles with missing data were contacted and given a 2-week period to respond.

Quality assessment of the studies was conducted independently by two authors (D.B. and K.E.), and any disagreement was solved by consensus. The Joanna Briggs Institute Critical Appraisal tools for cross-sectional studies[26] was used as an instrument for quality assessment.

This systematic review and meta-analysis was completed in adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines 2020[27] (Supplementary Table S1), and its registered protocol was submitted to the OSF platform (https://osf.io/vj586/).

Statistical analyses

A meta-analysis was conducted for studies in which the number of cigarettes before and during/after the COVID-19 lockdown was reported. Random effects in the meta-analytic model were used to estimate the differences of assessment effects in studies because of the high heterogeneity observed between studies. Furthermore, the weight of each study was calculated using the inverse variance method. Weighted mean difference was used because the outcome (number of cigarettes) was calculated using the same measurement scale (mean number of cigarettes and standard deviation). Assessment of the statistical heterogeneity between studies was calculated by the tau-squared and I^2 test. I^2 <25% indicated a low degree of heterogeneity, 25%–50% indicated moderate heterogeneity, and >50% to 70% showed significant heterogeneity. Percentages represented absolute changes in individuals' behaviours before and during/after lockdown. All statistical analyses were performed using the Review Manager (Version 5.4.1).

Results

Search results

A total of 14,848 studies were identified in the literature search up to 28 April 2022. After duplicate removal (n = 6905), 7943 studies were screened for eligibility. Subsequently, the application of inclusion and exclusion criteria led to 77 studies being included in this systematic review.[28–104] A flowchart of this process is presented in Fig. 1.

The characteristics of the included studies can be found in Tables 1 and 2. In total 207,841 adults from a significant geographical section of the globe (Albania, Australia, Bangladesh, Belgium, Brazil, Canada, China, Croatia, Cyprus, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, India, Italy, Israel, Jordan, Kuwait, Libya, Norway, Poland, Portugal, Romania, Russia, Slovenia, South Africa, Spain, Sweden, the Netherlands, Turkey, United Arab Emirates (UAE), The United Kingdom , Ukraine, The United States and Vietnam) were examined about their smoking and/or vaping behaviour. All the included studies had a cross-sectional design, except for one, which was a prospective cohort study.[77] The included studies assessed smoking/vaping behaviour using self-assessment questionnaires (online or not),[28–39,41–43,45,46,48–55,57–59,61–72,75–77,79,81,82,84,86–105] telephone interviews[40,44,47,56,73,78,80] or in-person interviews.[53,83,85,106]

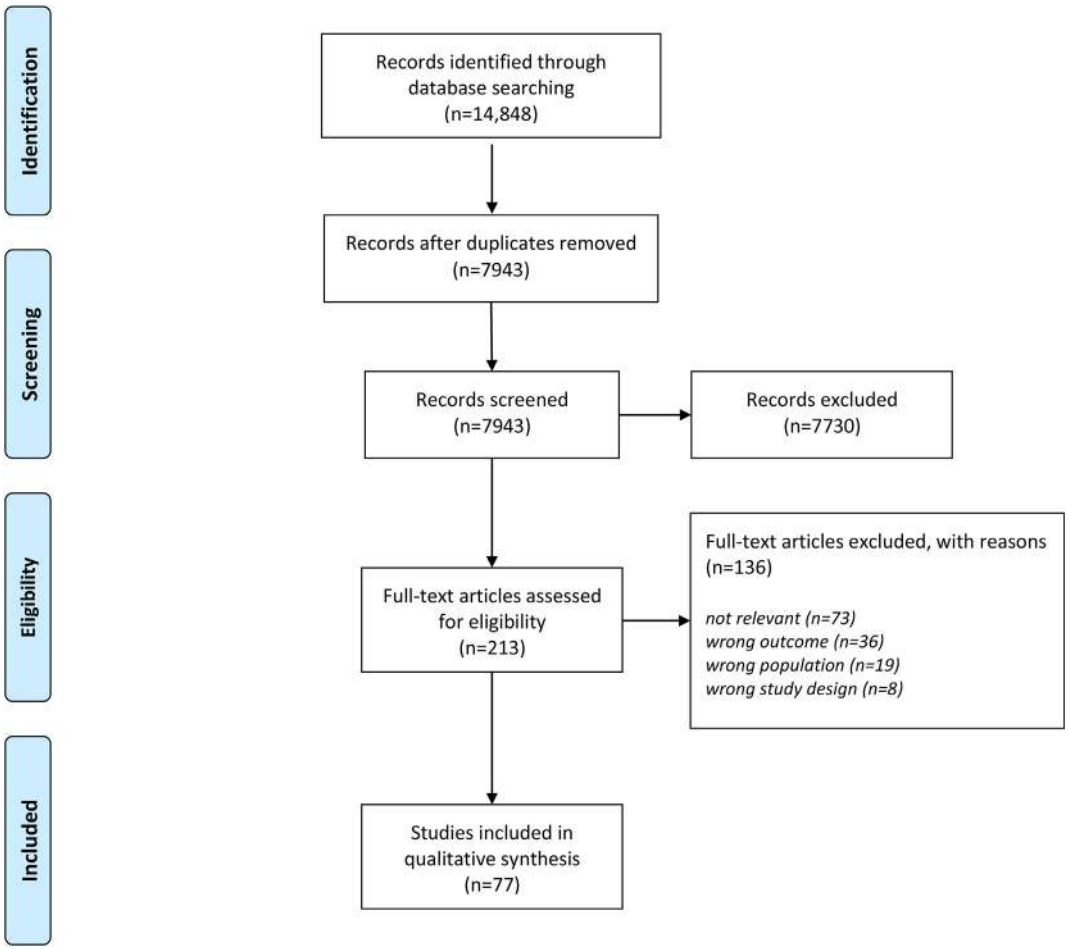

Fig. 1. Flow diagram of the study selection process.

Quality assessment

According to the Joanna Briggs Institute checklist for cross-sectional studies,[26] five of the 77 studies were characterised as 'best' in terms of quality, achieving high ratings in all domains.[64,73,82,87,99] All studies had appropriately defined inclusion criteria, and only two studies did not describe the subjects and settings in detail.[80,97] In most studies, biases and/or unclear statements were detected with reference to validation of exposure measures, criteria for measurement, identification of confounding factors and strategies to deal with the confounding factors.[28–63,65–72,75–81,83–86,88–98,100–105] With regard to outcome measurement, unclear information was provided in three studies,[45,78,101] and unclear statistical analyses were used in four[56,70,79,80] of 77 studies. Supplementary Table S2 provides full-quality assessment results.

Smoking behaviour

In 75 of 77 studies, information about smoking behaviour were reported[28-36,38-62,64-73,75-105] and can be found in Table 1. An increase in smoking habit was stated for most participants in 34 studies.[28,30–33,36,38,40,43,44,47–49,52,53,55,58,62,65,66,71,72,77,78,80,84,86,89,92,93,96,98,99,104,105] The change in smoking behaviour ranged from an increase of 0.4% in France[61] to 79.8% in Libya.[62] Countries that showed a clear increase in smoking habit were Belgium,[28,98] Cyprus,[65] Croatia,[48] Israel,[32] Jordan,[30] Libya,[62] Romania[105] and Turkey.[31,53,96] Moreover, in the study by Manthey et al. that included a population from 21 European countries, an increase in smoking habit was reported in 43.3% of participants.[71]

A decrease in smoking behaviour was reported for the majority of participants in 18 studies.[29,39,42,45,46,54,57,59,60,67,76,79,83,85,87,90,100–102] Countries that showed a clear decrease or cessation of smoking were Poland,[54] UAE[87] and Vietnam.[83] Data about the percentages of participants who quit smoking were available from Belgium,[28,98] Brazil,[45] France,[61,86] Germany,[66] India,[60,76] Italy,[38] Japan,[69,94] Romania,[105] Spain[39] and Turkey[96,101] and ranged from 1% to 73% of participants.

For 21 studies, the majority of participants reported no change in smoking behaviour.[34,35,41,50,51,56,61,64,68–70,73,75,81,82,89,91,94,95,97,103] Countries where smoking behaviour remained stable included Albania,[50] Canada,[95,103] Japan,[69,94] Kuwait[88] and the Netherlands.[51,97]

Within-country variations in the change of smoking behaviours were reported in Australia,[55,91,92] Bangladesh,[29,73] Brazil,[45,70,84] China,[99,100] France,[36,40,44,59,61,75,86] Germany,[66,81] India,[42,60,67,76,90,93] Italy,[38,43,46,47,52,78] Spain,[33,34,39,82] Sweden,[35,49] the United Kingdom[58,77,79,80] and the United States.[41,56,57,64,68,72,85,89,102,104]

Data regarding the change in the number of cigarettes smoked per day varied between countries. In India, 10% of participants stated that they smoked 4-6 cigarettes per day before the COVID-19 lockdown, whereas during/after the lockdown the percentage was 0.5%.[42] On the contrary, in one study from Brazil, despite the fact

Table 1
Baseline characteristics and smoking behaviour before and after/during COVID-19 lockdowns.

First author, year (country)	Subjects (F/M/O) type	Age (years)	Time of survey conduction	Smoking: increase	Smoking: decrease	Smoking: No change	Smoking: quit	No smokers	Initiation of smoking	Efforts to reduce smoking	Smoking before the COVID-19 lockdowns	Smoking after/during the COVID-19 lockdowns
Adriaens 2021 (Belgium)[28]	202 (50/150/2)	≥18/39 (9.89)[a]	25 May to 8 June 2020	42.4%	16.9%	10.2%	30.5%					
Ahmed 2021 (Bangladesh)[29]	1222 (466/750)	18–82/ 30.8 (12.1)[a]	27 June to 20 July 2020	6.4%	48.6%	45%						
Al Domi 2021 (Jordan)[30]	4388 (3086/1302)	NA	March to April 2020	13.3%				71.4%				
Ayran 2021 (Turkey)[31]	503 (234/269)	21.6 (2.5)[a]	May to June 2020	32.4%						Yes: 41.9% No: 58.1%		
Bar-Zeev 2021 (Israel)[32]	660 (397/263)	40.2 (14.55)[a]	6–28 April 2020	44.3%	21.2%	34.5%				Yes: 16%		
Biviá-Roig 2021 (Spain)[33]	124 (124/0)	18–38/ 33.5 (3.7)[a]	28 October 2020	27.5%				72.5%				
Blithikioti 2021 (Spain)[34]	303 (186/113) Subjects with substance use disorders	49.3 (15.6)[a]	June to July 2020	5.4%	9.5%	85.1%					Never: 42.9% 1–2 times/year: 3.1% Monthly: 1% Weekly: 3.4% Daily: 49.7%	Never: 47.5% 1–2 times/year: 4% Monthly: 1.3% Weekly: 2.6% Daily: 44.6%
Blom 2021 (Sweden)[35]	5599 (2800/2800)	46.3 (11.0)[a]	21 April to 2 December 2020	1st wave (April to June): 0.8% 2nd wave (September to December): 0.5%	1st wave (April to June): 3.8% 2nd wave (September to December): 2.5%	1st wave (April to June): 95.4% 2nd wave (September to December): 97%						
Bourion-Bedes 2021 (France)[36]	3928 (2771/1154)	21.7 (4)[a]	7–17 May 2020	7.2%	6.3%	3%		83.5%				
Carreras 2021 (Italy)[38]	1400 (677/724) Current smokers	18–74	27 April to 3 May 2020	36.3%	15%		8.6%					
Celorio-Sardà 2021 (Spain)[39]	321 (256/65)	≥18	22 May to 3 July	22%	30%		15%	87.5%				
Chagué 2020 (France)[40]	124 (49/75) Subjects with congestive heart failure	71.0 (14.0)	17–24 March 2020	44.4%				92.7%				
Chertok 2020 (USA)[41]	180	≥18	Initiation on 7 April 2020	18.3%	21.3%	43.3%						
Chopra 2020 (India)[42]	995	18-85/ 33.3 (14.5)[a]	15–30 August 2020								No: 94.4% Yes, 1-3 cigarettes/day: 3.7% Yes, 4-6 cigarettes/day: 10% Yes, 7-9 cigarettes/day: 0.7% Yes, >10 cigarettes/day: 0.2%	No: 95.3% Yes, 1-3 cigarettes/day: 3.9% Yes, 4-6 cigarettes/day: 0.5% Yes, 7-9 cigarettes/day: 0.0% Yes, >10 cigarettes/day: 0.3%
Cirilo 2021 (Italy)[43]	140 Infertile women	18–49/ 39.4 (5)[a]	20 April to May 2020	27.3% *(of smokers)*								

(*continued on next page*)

Table 1 (*continued*)

First author, year (country)	Subjects (F/M/O) type	Age (years)	Time of survey conduction	Smoking: increase	Smoking: decrease	Smoking: No change	Smoking: quit	No smokers	Initiation of smoking	Efforts to reduce smoking	Smoking before the COVID-19 lockdowns	Smoking after/during the COVID-19 lockdowns
Cransac-Miet 2020 (France)[44]	195 Patients with chronic coronary syndromes	65.5 (11.1)[a]	April 2018 to April 2019	Smoking increase (>25%): 24.1%								
da Silva Leonel 2021 (Brazil)[45]	1515 (1120/395)	18–80/ 31.8 (11.5)[a]	June to July 2020				29.8%	90.5%	0.7% *of non-smokers*		>10 cigarettes/day: 11.9% 1–10 cigarettes/day: 51.5% No: 74.9% <5 cigarettes/day: 8.9% 5–10 cigarettes/day: 8.3% >10 cigarettes/day 7.9%	>10 cigarettes/day: 29.7% 1–10 cigarettes/day: 35.6% *P < 0.001* No: 78.2% <5 cigarettes/day: 8.2% 5–10 cigarettes/day: 6.3% >10 cigarettes/day 7.3%
Di Renzo 2020 (Italy)[46]	3533 (2689/844)	40.03 (13.53)[a]	5–24 April 2020									
Di Santo 2020 (Italy)[47]	126 (102/24) Subjects with mild cognitive impairment or subjective cognitive decline	≥60/ 74.29 (6.51)[a]	21 April to 7 May 2020	33.3%	11.1%			85.71%				
Dogas 2020 (Croatia)[48]	3027 (1989/506)	40 (30-50)[b]	25 April to 5 May 2020								Number of cigarettes: 12.3 (7.8)[a]	Number of cigarettes: 14.3 (10.3)[a]
Ekstrom 2021 (Sweden)[49]	1064 (996/648)	25.3 (0.8)[a]	10 August to 10 November 2020								No: 68.8% Former smokers: 12.3% Occasionally: 12.4% Daily: 6.5%	No: 71.7% Former smokers: 13.6% Occasionally: 11% Daily: 3.7%
Elezi 2020 (Albania)[50]	1678 (1229/449)	26.49 (8.07)	4–29 April 2020	20.8%	39.1%	40.1%		87.7%				
Elling 2020 (The Netherlands)[51]	340 (207/133) Smokers willing to quit smoking	21–80 49 (13)[a]	26 March to 3 April 2020	13.8%	18.5%	67.7%						
Ferrante 2020 (Italy)[52]	7847	48.6 (13.9)[a]	21 April to 7 June 2020	29.5%								
Fidanci 2021 (Turkey)[53]	104 (50/54)	37.4 (10.7)[a]	May to November 2020								Very low dependence: 26.9% Low dependence: 16.3% Moderate dependence: 15.4% High dependence: 18.3% Very high dependence: 23.1%	Very low dependence: 14.4% Low dependence: 20.2% Moderate dependence: 14.4% High dependence: 23.1% Very high dependence: 27.9%
Fila-Witecka 2021 (Poland)[54]	980 (733/247)	22.24 (2.46)[a]	12 May to 30 June 2020	11%	16%							
Gendall 2020 (Australia)[55]	261 (128/133)	≥18	15–18 April 2020								Daily smokers: 11.1% Weekly smokers: 9.1%	Daily smokers: 13% Weekly smokers: 9.5%
Gonzalez 2021 (USA)[57]	2571	≥18	March to May 2020								Number of cigarettes: 13 (8.91)[a]	Number of cigarettes: 11.8 (7.8)[a]
Giovenco 2021 (USA)[56]	44 (24/20) Smokers	≥18	14–24 April 2020	18.2%	13.6%	68.2%						
Grogan 2020 (UK)[58]	132 (73/55/4) Smokers	25 (19-52)[b]	22 May to 22 June 2020	12%								
Guignard 2021 (France)[59]	2003 (1049/954)	≥18	30 March to 1 April 2020	26.7%	38.3%			78.9%				
Gupte 2020 (India)[60]	650 Smokers		14–28 May 2020				34%					
Hansel 2021 (France)[61]	5280 (2677/2587/16)		23–28 April 2020	0.4%	3.3%	90.1%	2.3%					

Jahan 2021 (Libya)[62]	683 (399/284)	≥18	10 October to 10 November 2020	79.8%				85.6%				
Knell 2020 (USA)[64]	1809 (1220/589)	35–49	15 April to 5 May 2020	30.5%	19.2%	50.3%		74.7%				
Kolokotroni 2021 (Cyprus)[65]	745 (550/195)	39 (13)[a]	10 April to 12 May 2020	43.8%	28.1%							
Koopmann 2021 (Germany)[66]	3116	≥18	8 April to 11 May 2020	45.8%	9.0%	31.3%	9.9%	75.7%	4.0%			
Kovil 2020 (India)[67]	343 (110/233) Subjects with T2DM	55 (13.0)[a]	10–16 April 2020								12.2%	8.4%
Kowitt 2020 (USA)[68]	777 (380/389)	39.9 (13.4)[a]	23 April to 7 May 2020	40.9%	17.8%	41.3%				Yes: 46.5%		
Koyama 2021 (Japan)[69]	5120 (2505/2615) Smokers		27 May to 14 June 2020	32.1%	11.3%	44.8%	11.9%					
Malta 2021 (Brazil)[70]	45,161 (26,206/18,955)	≥18	24 April to 24 May 2020	34% (6.4% increase 1-5 cigarettes, 22.5% increase 10 cigarettes, 5.1% increase >20 cigarettes)	12.1%	53.9%		88%				
Manthey et al., 2021 (21 European countries)[71,c]	9816 (4574/5114/128) Smokers	18–98	24 April to 22 July 2020	43.3%	39.6%	17.1%						
Matsungo 2020 (USA)[72]	507 (283/166)	≥18	11–25 May 2020	6.6%	4%	3.7%		85.7%				
Mistry 2021 (Bangladesh)[73]	1032(676/356)	≥60	October 2020	15.9%		84.1%		54.4%				
Mititelu 2021 (Romania)[74]	805 (158/647)	≥20	8–26 July 2020	17.8% (of smokers)			1.8%	70.1%				
Mounir 2021 (France)[75]	702 (564/138)	≥18	18 May to 6 June 2020	24%	4.1%	71.5%						
Naik 2021 (India)[76]	116 (10/106)	>18	December 2020		60.3%	24.1%	27.6%	67.4%				
Naughton 2021 (UK)[77]	1044 (747/279/2)	≥18	8 April to 18 May 2020					63.8%			9.6%	10.8%
Odone 2021 (Italy)[78]	6003	18–74	27 April to 3 May 2020	44%	24%	28%						
O'Donnell 2021 (UK)[79]	25 (12/13)	22–73	September to November 2020								23.3%	21.9%
Osinibi 2021 (UK)[80]	50		January to February 2021	32%	34%	34%						
Palmer 2021 (Germany)[81]	827 (622/205)	18–29	12 March to 3 May 2020	4.9%	5.4%	89.7%						
Pérez-Rodrigo. 2021 (Spain)[82]	1036 (735/301)	≥18	21 April to 8 May 2020	14.1%	14.7%	16.5%						
Pham 2020 (Vietnam)[83]	8291 (4890/3401)	18–85	14 February to 31 May 2020									Never, stopped, or smoke less: 91% Unchanged or smoke more: 9%
Prezotti 2021 (Brazil)[84]	275 (26/249)	30 years (28-31)[b]	11–19 June 2020	53.6% (of smokers)	7.1%			88.6%				
	694 (414/280)	≥18		32%		31%						

(continued on next page)

Table 1 (*continued*)

First author, year (country)	Subjects (F/M/O) type	Age (years)	Time of survey conduction	Smoking: increase	Smoking: decrease	Smoking: No change	Smoking: quit	No smokers	Initiation of smoking	Efforts to reduce smoking	Smoking before the COVID-19 lockdowns	Smoking after/during the COVID-19 lockdowns
Rigotti 2021 (USA)[85]			18 May to 16 July 2020		37% (including 8% quit)							
Rossinot 2020 (France)[86]	1454 (924/523/7)	24–65	23 April to 7 May 2020	11.2%	6.3%	10.2%	72.3%					
Saddik 2021 (UAE)[87]	1469 (1216/253)	≥18	24 March to 15 May 2020	Started/ increased: 13%	Stop/ decreased: 49%							
Salman 2021 (Kuwait)[88]	679 (393/286)	≥21	19 June to 15 July 2020	9.1%	5%	10.3%		75.6%				
Sharma 2020 (USA)[89]	542 (436/106)	18–25/ 22 (2.1)[a]	April to May 2020	8.3%	16.2%			75.5%				
Singh 2021 (India)[90]	10,008	18–81	20 May 2020								I don't smoke: 87%/party smoker: 6.5%/at least 1 cigarette/day: 6.4%	I don't smoke: 94.3%/party smoker: 2.4%/at least 1 cigarette/day: 3.3%
Stanton 2020 (Australia)[91]	4183 (999/484)	50.5 (14.9)[a]	9–19 April 2020	6.9% (negative change)	3.4% (positive change)	89.7%						
Stubbs 2021 (Australia)[92]	317 (227/89/1)	>18	Mid-March 2020 to the end of May 2020	56%	10%	33%		88.9%				
Sujatha 2021 (India)[93]	729 (132/597)	44.1 (14.4)[a]	NA	69%	49%	22%						
Suka 2021[94] (Japan)	8000 (4000/4000)	25–64	November 2020	2.2%	3.8%	81.5%	12.4%					
Tavolacci 2021 (Canada)[95]	3671 (2676/995)	20.9 (2.47)[a]	13–31 May 2020	2% (unfavourable change)	5.8% (favourable change)	92.2%					Regular: 14% Occasional: 4.5%	Regular: 12.4% Occasional: 2.4%
Uysal 2021 (Turkey)[96]	615 (422/193)	18–90	30 June to 30 September 2020	18.2% (initiation) 15.9% increase	14.5%		12.2%					
Van der Werf 2021 (The Netherlands)[97]	1004 (509/495)	≥18	22–27 May 2020	3.7%	8.3%	59.3%		Unknown: 28.8%				
Vanderbruggen. 2020 (Belgium)[98]	3632	42,1 (14.6)[a]	9–29 April 2020	0.9% *(initiation)* 7.4% *(increase)*	2.5%		1%					
Yan 2020 (China)[99]	9016 (5177/3839)	≥18	25 April to 11 May 11 2020	49.2%	28.5%	22.3%						
Yang 2021 (China)[100]	11,500 (5635/5865)	36.79	October 2020	14.9%	18.5%	8.7%		57.9%				
Yenibertiz 2021 (Turkey)[101]	105 (42/63)	39.80 (12.66)[a]	March to June 2020				13.3%					
Yingst 2021 (USA)[102]	291 (216/75)	47.3 (11.6)[a]	23 April 2020								93.1%	90.4%
Zajacova 2020 (Canada)[103]	4319 (2202/2117)	≥25	29 March to 3 April 2020	3%	4%	93%						
Zhang 2021 (USA)[104]	1276 (517/724)	45.0 (17.0)[a]	13 April to 8 June 2020	41%	20.1%	38.9%						

F, female; M, male; NA, not applicable; O, other; T2DM, type 2 diabetes mellitus.
All studies were cross-sectional except for the Naughton 2021, which was a prospective cohort study. Percentages represent absolute changes.
[a] Mean (standard deviation).
[b] Median (interquartile range).
[c] Albania, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Norway, Poland, Portugal, Russia, Slovakia, Slovenia, Spain, Sweden, Ukraine and the United Kingdom.

Table 2
Characteristics of vaping habit before and after/during COVID-19 lockdowns.

Study ID (country)	Subjects (F/M/O) Type	Age (years)	Time of survey conducting	Vaping: increase	Vaping: decrease	Vaping: no change	Vaping: quit	Vaping before COVID-19 lockdown	Vaping after/during COVID-19 lockdown
Adriaens 2021 (Belgium)[28]	202 (50/150/2)	≥18/39 (9.89)[b]	25 May to 8 June 2020	25.4%	27.1%	40.7%	6.8%[a]		
Caponnetto 2020 (Italy)[37]	1825 (683/1142)	34.7 (14.11)[b]	2–26 April 2020	22.3%	6.5%	34.8%			
Giovenco 2021 (USA)[56]	44 (24/20) Smokers	≥18	14–24 April 2020	2.3%	6.8%	4.5%			
Kale 2021 (UK)[63]	2792 (1452/1340)	NA	30 April to June 2020	42.1%	9.5%				
Odone 2021 (Italy)[78]	6003	18–74	27 April to 3 May 2020					8.1%	9.1%
Yingst 2021 (USA)[102]	291 (216/75)	47.3 (11.6)[b]	23 April 2020					16.2%	13.1%
Zhang 2021 (USA)[104]	1276 (517/724)	45.0 (17.0)[b]	13 April to 8 June 2020	45.9%	18.2%	35.9%			

F, female; M, male; O, other.
All studies were cross-sectional. Percentages represent absolute changes.
[a] All, ran out of e-liquid.
[b] Mean (standard deviation).

that 29.9% of smokers quit smoking, the percentage of subjects who smoked >10 cigarettes per day increased from 11.9% before the COVID-19 lockdown to 29.7% during/after the COVID-19 lockdown ($P < 0.001$).[45]

Meta-analysis results, where data from five cross-sectional studies were analysed,[32,48,57,98,102] showed a tendency towards an increase in the number of cigarettes smoked per day; however, this change was not significant (0.81 weighted mean difference [95% confidence interval, −0.59 to 2.21]), and there was high heterogeneity among studies ($I^2 = 94\%$). The results of the meta-analysis can be seen in the forest plot in Fig. 2.

Vaping behaviour

Vaping behaviour was reported in seven of 77 studies.[28,37,56,63,78,102,104] In two studies, from Belgium[28] and Italy,[37] most of the participants stated that their vaping behaviour was not changed during/after the COVID-19 lockdown. An increase in vaping habit during/after COVID-19 lockdown was observed in three studies, led by Kale,[63] Odone[78] and Zhang.[104] On the other hand, a decrease in vaping habit was recorded in the studies by Giovenco et al.[56] and Yingst et al.[102] Information regarding vaping cessation was only provided by one study from Belgium, where 6.8% of participants quit this habit during/after COVID-19 lockdown.[28]

Discussion

Smoking and vaping behaviours are impacted by the COVID-19 lockdown. To the best of the authors' knowledge, this is the first systematic literature review and meta-analysis that aimed to investigate the impact of the COVID-19 lockdowns on smoking and vaping behaviour.

Regarding smoking behaviour during/after lockdown, an 'increase' was the predominant answer ($N = 35$), followed by the statement of 'no change' ($N = 21$). A decrease in smoking behaviour by the majority of participants was found in 19 studies.

Different results regarding smoking behaviour change during/after lockdown have been observed in France.[36,40,59,61,75,86] An increase in smoking was reported for participants in the studies by Borion-Bédès et al.[36] and Rossinot et al.,[86] which included the general population. Similarly, an increase in smoking behaviour was the predominant answer in the study by Chagué et al. in which participants with congestive heart failure were the target population[40] and in the study by Cransac-Miet et al.[44] that investigated a population of individuals with chronic coronary syndromes. On the other hand, the fact that more than one-third of participants decreased their smoking behaviour in the study by Guignard et al.[59] and that 'no change' was the predominant answer in the studies led by Hansel[61] and Mounir[75] reflects the heterogenous populations that were included in the French studies. It is important to highlight the fact that participants with coronary syndromes increased their smoking behaviour during/after lockdown, thus also increasing their risk of acute coronary events and complications.[107]

With regard to Germany, in one study that was conducted over a 1-month period (April to May 2020), an increase in smoking behaviour was reported for almost half of the participants.[66] However, the study led by Palmer that was conducted for a more representative period of the first lockdown indicated that the 'no change' answer was the predominant response, and this could be more representative for the country.[81]

Most studies from Italy showed an increase in smoking behaviour during/after lockdown.[38,43,47,52,78] The populations in these studies varied significantly, including the general population,[78] current smokers,[38] infertile women[43] and elderly individuals with

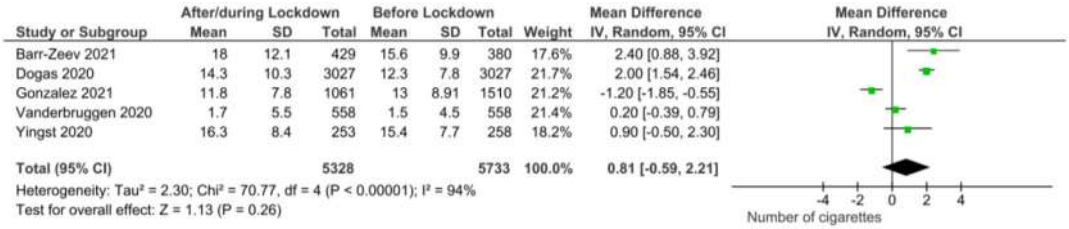

Fig. 2. Forest plot of the number of cigarettes smoked per day before and after/during the COVID-19 lockdown.

cognitive impairment.[47] Of special interest is the fact that infertile women increased their smoking behaviour, whereas it is already known that smoking has a negative impact in female fertility.[108] Only one study from Italy reported a decrease in smoking behaviour. This study included the general adult population, but further information regarding the sample was missing.[46]

Information regarding change in smoking behaviour during/after lockdown in Spain came from four studies.[33,34,39,82] An increase in smoking was reported for almost one-third of participants in the study by Biviá-Roig. This study took place during the second lockdown (October 2020) with a small sample (n = 124 women);[33] therefore, the results might not be representative for the whole country. A decrease in smoking was stated in the cross-sectional study led by Celorio-Sardà,[39] where 30% of smokers reduced their smoking habit and 15% reported having quit smoking. In the study by Perez-Rodrigo, information regarding more than half of the participants' smoking habits was missing, and the interpretation of the results of this study cannot be accurate.[82] In addition, in the study by Blithikioti et al., where a subgroup of participants with substance use disorder from Spain were examined, approximately 85% of participants stated that they did not change their smoking behaviour and almost 10% reduced this habit.[34] These results are in accordance with a study from England that examined drinking and smoking changes during the COVID-19 lockdown, where an increase in smoking cessation attempts was found.[25] A possible explanation could be that this vulnerable population group could be more motivated and focussed to overcome addictions during the lockdown.

The results from Sweden showed that when it came to both the first and second wave of lockdowns, smoking habit was not changed for the majority of participants. In contrast, in a study that was conducted between August and November 2020, a decrease in smoking was observed.[49] However, Sweden was not under restriction measures during this whole period; therefore, lockdown might not be the only factor that had an impact on the decrease in smoking behaviour.

In the United Kingdom, three of four studies showed an increase in smoking behaviour for the majority of participants,[58,77,80] whereas smoking prevalence was found to decrease in the study led by O'Donnell.[79] The difference in these results could be explained by the fact that the study by O'Donnell et al. was conducted between September and November 2020 when there were periods with and without lockdown;[79] therefore, the results from this study might not be representative for the lockdown period.

In the United States, most participants stated that they did not change their smoking behaviour during the lockdown.[41,56,64,68] An increase in smoking behaviour was observed for most of the smokers in the studies by Matsungo et al.,[72] Sharma et al.[89] and Zhang et al.[104] On the contrary, 'decrease' was the predominant answer in the studies led by Rigotti[85] and Yingst.[102] All the US studies included general adult populations.[41,56,64,68,72,85,89,102] The heterogeneity between the results could be explained by the fact that each study included populations that may not be representative for the whole country; however, the results provide some initial evidence about smoking behaviour in the United States.

In Brazil, heterogeneity in the results between studies was observed.[45,70,84] The period that the surveys were conducted was not the same among these three studies and could explain the difference in the results. Most of the participants stated that they did not change their smoking behaviour early in lockdown (April to May 2020).[70] However, 1 month later (June 2020), an increase was observed for more than half of the smokers, showing June as the period of the greatest impact of lockdown.[84] Between June and July 2020, when lockdowns were reduced and daily life seemed to get back to normal, cessation of smoking was seen in almost one-third of smokers, and smoking initiation was observed for <1% of the participants.[45] Nevertheless, the number of cigarettes smoked per day was found to increase, and this could mean that subjects who increased smoking either continued their harmful habit or quitted smoking with a view to limit factors that could worsen any potential COVID-19 infection.[45]

Heterogenicity in results was also observed in studies from Bangladesh.[29,73] The study by Ahmed et al.,[29] which was conducted during the period of the first lockdown (27 June to 20 July 2020) showed that smoking habit decreased for most participants, whereas in the study by Mistry et al.,[73] which was conducted during the second lockdown (October 2020), 'no change' was the predominant response. This could be because people tried to decrease their smoking habits at the start of the pandemic, possibly due to the fear of this respiratory disease, whereas the second lockdown did not have the same impact on the lifestyles of participants.

Moreover, in China, during April and May 2020, almost half of the participants increased their smoking behaviour,[99] whereas a decrease was observed for most participants during October 2020, which reflected the beginning of the second COVID-19 lockdown.[100] The difference between the two lockdowns showed that the first lockdown negatively influenced the daily life of people, possibly due to the fear and stress of the COVID-19.[109]

All studies from India[42,60,67,76,90] reported a decrease and/or cessation of smoking for most participants, except one showed, which showed an increase.[93] According to Gupte et al.,[60] the reasons that participants decreased their smoking behaviour included the increased price, the unavailability of tobacco and the concerns about COVID-19. From another point of view, the high rate of increase in smoking reported in Sujatha et al.[93] was explained by the fact that smokers bought more smoking products due to the fear that stores would run out of stock and the lockdown would be extended. However, the period when the survey was conducted in this study was not reported, and therefore, it was difficult understand the disagreement of the results compared with the other studies from India.[93]

In the studies from Australia, an increase in smoking habit was stated in two of three studies,[55,92] and the 'no change' answer was the most predominant in the study by Stanton et al.[91] Studies led by Gendal and Stanton were both conducted during April 2020;

however, in the Gendal et al. study, data from almost 80% of participants were missing, meaning that the impact of lockdown during April 2020 in Australia was not clear in the results.[55,91] Taking into account the fact that the study led by Stubbs was conducted from mid-March until the end of May 2020, which was a more representative period of lockdown, the increase in smoking behaviour for most smokers may be the most accurate results for change in smoking behaviour in Australia.[92]

In general, lockdowns changed smoking behaviour. Smoking, which in most cases was found to increase during/after lockdown, has been associated with more severe COVID-19 infection and worse outcomes according to recent systematic reviews.[110,111] In addition to the risk of a more severe COVID-19 infection, the increase of smoking can lead to smoking-related illnesses, such as cancer,[112] heart diseases,[113,114] lung impairments[115] and diabetes mellitus type 2.[116] Smoking can also increase the risk eye diseases[117] and immune system disorders, such as rheumatoid arthritis.[118]

Meta-analysis results of the number of cigarettes smoked per day showed a tendency towards an increase, but this was not statistically significant (Fig. 2). Interpretation of these results could be that there is a trend towards increase. However, the high heterogeneity among the studies included in the meta-analysis cannot lead to firm conclusions.

The results on vaping behaviour showed a tendency towards an increase during/after lockdown in most studies.[63,78,104] Information regarding vaping behaviour reflected only the first COVID-19 lockdown (April to June 2020).[28,37,56,63,78,102,104] Studies from the United States showed different results for vaping behaviour.[102,104] The study of Yingst et al.[102] showed a decrease in vaping prevalence, although it should be noted that this was a 1-day survey with a small sample ($N = 291$). The results from the study by Zhang et al.,[104] which took place over almost 3 months and included a larger sample ($N = 1276$), could be more representative of the United States. An increase in vaping behaviour, which is promoted as a safer alternative to smoking, could also lead to detrimental health effects due to the fact that electronic cigarette use has been associated with severe acute and chronic lung injuries.[119,120]

The present study has several strengths. First, to the best of the authors' knowledge, this is the first systematic review and meta-analysis to examine the impact of the COVID-19 lockdown on smoking and vaping. The 77 studies included are from a large geographical section of the globe, results reflect both COVID-19 lockdowns, and provide a representative impact of the pandemic on smoking and vaping behaviour, as more than 207,000 adults were included. Moreover, the quality of included studies was sufficient, which strengthens the present study results.

Among the limitations of the present study is the missing information about the representativeness of each study sample. In addition, the level of statistical significance and the level of change in smoking behaviour were not reported in most of the studies included in the systematic review. Moreover, this study did not investigate the impact of lockdowns on heated tobacco, and it is not known whether the term 'smoking' in some studies included heated tobacco or not. In addition, the fact that different measures were used to assess smoking/vaping behaviour may influence the accuracy of the existing data. Furthermore, only studies in English, French and Spanish languages were included in this analysis; thus, relevant studies in other languages were missing.

Conclusions

According to most included studies, smoking and vaping habits increased during the lockdowns.

However, for a minority of participants, the fear of COVID-19 was a motivation to quit smoking/vaping. The increase in smoking and vaping behaviours could have a detrimental health impact in both the short and long term. If such changes remain for a long time or become permanent, the prevalence of non-communicable diseases is expected to increase. Therefore, in addition to strategies advocating for healthier lifestyles overall, further research is needed in this field. Awareness of the benefits of smoking/vaping cessation may be important for the reversal of this unhealthy habit.

Author statements

Ethical approval

Ethics approval was not required for this study. This study is a review, and data were freely available in the literature.

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Competing interests

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Authors' contributions

D.B., K.E and A.S. searched the databases. D.B, K.E, A.S. and M.C. wrote the article. D.B., J.B., and M.C. made the necessary recommendations. and D.B., J.B., and M.C. revised the article. All authors have read and approved the final version of article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2023.02.007.

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Original Research

Indirect impact of the COVID-19 pandemic on the incidence of non–COVID-19 infectious diseases: a region-wide, patient-based database study in Japan

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ABSTRACT

Objectives: The COVID-19 pandemic has forced people to change many behaviours, including physical distancing, hygiene measures and lifestyles. This study aimed to evaluate the indirect impact of the COVID-19 pandemic on the incidence of non–COVID-19 infections and medical care costs/visits using health insurance claims.

Study design: This was an observational study using patient-based administrative claims covering approximately 800,000 insured persons and their dependents in the Mie Prefecture in Japan.

Methods: This study identified non–COVID-19 infectious disease incidences, number of outpatient visits and healthcare costs between 2017 and 2021. Each year was divided into quarters. The adjusted incidence rate ratios (IRRs) during the pandemic (January 2020 to September 2021) and during the prepandemic period (January 2017 to December 2019) were determined using Poisson regression.

Results: The adjusted influenza IRRs from April 2020 were close to zero. The incidence of upper respiratory tract infections and bacterial pneumonia was significantly reduced (IRRs range: 0.39–0.73 and 0.43–0.84, respectively). Gastrointestinal and urinary tract infection incidences decreased by approximately 30% and 10%, respectively. In contrast, sexually transmitted infections (STIs), including syphilis, gonococcal infection and *Chlamydia trachomatis* infection, did not decrease during the pandemic but increased significantly between April and June 2021 (adjusted IRR, 1.37; 95% confidence interval, 1.18–1.60). The adjusted IRRs for outpatient visits and healthcare costs were 0.86–0.93 and 0.91–0.97, respectively.

Conclusions: In contrast to other infections, STIs did not decrease during the COVID-19 pandemic. The IRR of STIs during the pandemic period is an area of public health concern. Appropriate screening and medical consultations are strongly recommended.

Introduction

COVID-19 was first identified in Wuhan, China, in December 2019 and has spread worldwide, resulting in a global pandemic.[1] The emergence of COVID-19 led to the implementation of physical/social distancing measures, such as lockdowns, restrictions on movement between countries and wearing masks in many regions, which had a substantial impact population behaviours and lifestyles. Healthcare institutions, including clinics and hospitals, have been forced to redeploy resources to cope with COVID-19, thus impacting their ability to provide other healthcare services.[2] Furthermore, the COVID-19 pandemic and physical/social distancing changed behaviours around attending medical appointments.[3,4] As a result of these factors, the COVID-19 pandemic had an indirect impact on the incidences of other infectious

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diseases.[5–9] A previous report using claims data from 262 Japanese hospitals found a 48% reduction in the number of inpatient cases of community-acquired pneumonia.[5] Similar studies from Italy and England also reported an indirect impact on the incidence of community-acquired infections.[7,8] However, previous reports were mostly limited to hospital-based studies and lacked data regarding outpatient settings. Studies using patient-based databases covering all medical care provided to individuals are warranted to evaluate epidemics of infectious diseases.

The first case of COVID-19 in Japan was reported in January 2020. The Japanese government declared a nationwide state of emergency between April and May 2020 and between January and February 2021, and quasi-emergency measures were implemented several times, depending on the prefecture. Under these measures, citizens were requested to stay home, and business services, such as restaurants or mass-gathering events, were restricted or suspended.[10] In Japan, many citizens have been wearing masks outside their homes and implementing physical/social distancing measures since the COVID-19 outbreak. To evaluate the indirect impact of the COVID-19 pandemic on the incidence of other infectious diseases, this investigation conducted a descriptive study using a region-wide patient-based claims database in Japan.

Methods

Data sources

An observational study was conducted using the administrative health insurance claims database of the Mie Prefecture, which is in the central region of Japan and had a population of approximately 1.8 million between January 2017 and September 2021. In Japan, all citizens are enrolled in a universal health coverage insurance programme provided by the social insurance system (for employees aged <75 years), the national health insurance system (for self-employed or unemployed people aged <75 years) and the late elders' health insurance system (for people aged ≥75 years). The database used in the present study covers approximately 800,000 residents in the Mie Prefecture (44% of the population) who were beneficiaries of the National Health Insurance or the Late Elders' Health Insurance System. Accordingly, participants in this study were likely to be older than the general Japanese population. The database comprises medical and pharmacy claims. Medical and pharmacy claims are linked using anonymised identification numbers, which are specifically generated by combining sex, birthdate and insurance identification numbers. Monthly information on patient demographics, including year and month of birth, sex, diagnosis, date of diagnosis, medical procedures and medications are provided. Diagnoses were recorded by physicians of each medical facility and coded according to the International Classification of Diseases and Related Health Problems, 10th Revision (ICD-10). This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Jichi Medical University Hospital (approval number 21-198). The requirement for informed consent was waived owing to the retrospective study design and use of anonymised data.

Data preparation and measures

Medical and pharmacy claims in the database were linked using the unique identification number for each individual, and incidences of non–COVID-19 infectious diseases were identified. The non–COVID-19 infectious diseases analysed in the study were as follows: influenza, upper respiratory tract infection (URI), bacterial pneumonia, gastrointestinal infections, urinary tract infection (UTI), syphilis, gonococcal infection and *Chlamydia trachomatis* infection. Each non–COVID-19 infectious disease was defined by ICD-10 codes as follows: influenza (J10, J11), URI (J00–J069), bacterial pneumonia (J13–J16, J18), gastrointestinal infections (A00–A05, A08, A09), UTI (N10, N12, N151, N300, N309, N390), syphilis (A51–A53), gonococcal infection (A54) and *C. trachomatis* infection (A55, A56). Of these infections, syphilis, gonococcal and *C. trachomatis* infections were defined as a combination of ICD-10 codes and diagnostic tests (serological testing for syphilis and chlamydia, nucleic acid amplification or antigen detection testing for *Neisseria gonorrhoeae* and *C. trachomatis*) within 7 days of the date of diagnosis. Similarly, bacterial pneumonia and UTI were defined as a combination of ICD-10 codes and systemic antibiotic prescriptions (Anatomical Therapeutic Chemical classification code J01) within 7 days of the date of diagnosis. The diagnosis code of the same disease appearing within 90 days was considered the same event and excluded. Sexually transmitted infections (STIs) are defined as the total number of syphilis, gonococcal and *C. trachomatis* infections. Admission due to bacterial pneumonia was defined as a combination of ICD-10 codes, systemic antibiotic prescription within 7 days of diagnosis and admission within 7 days of diagnosis; the proportion of hospitalisations for bacterial pneumonia was calculated. If the incidence per month was less than 10, an accurate number of incidences would not be disclosed to protect personal confidence. Furthermore, data on the total number of outpatient visits and healthcare costs were extracted from medical and pharmacy claims.

Data analyses

Monthly crude incidences and trends for non–COVID-19 infectious diseases, the number of outpatient visits and healthcare costs were described. The study duration was divided into two periods: before (January 2017 to December 2019) and during (January 2020 to September 2021) the COVID-19 pandemic. Each year was divided into quarters (January to March, April to June, July to September and October to December), and event incidences in the pandemic period were compared with the prepandemic period. The incidences were adjusted for the annual number, age and sex of the insured persons and their dependents. Adjusted incidence rate ratios (IRRs) were estimated using Poisson regression. The proportion of hospitalisations for bacterial pneumonia was compared before and during the COVID-19 pandemic using the Chi-squared test. All hypothesis tests were two tailed, with a significance level of 5%. All statistical analyses were performed using R (version 4.1.1; R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 800,444 insured individuals and their dependents were identified in 2017. Of these, 53,197 (6.6%), 242,733 (30.3%) and 504,514 (63.0%) were aged <20 years, 20–64 years and ≥65 years, respectively. The trend in the annual number of insured persons, including their dependents, is shown in Supplementary Table S1.

Fig.1 shows the trends of monthly crude incidences of non–COVID-19 infectious diseases from January 2017 to September 2021. Influenza events declined dramatically, almost to the point of cessation, from April 2020. In the influenza season, 33,862 and 23,145 events were identified during the 2017–2018 and 2018–2019 seasons, respectively, whereas 11,878 events occurred during the 2019–2020 season, and only 65 events were identified during the 2020–2021 season. During the COVID-19 pandemic, the number of URI and bacterial pneumonia events also decreased by half compared with prepandemic numbers.

The monthly crude incidences of non–COVID-19 infectious diseases, number of outpatient visits and healthcare costs are shown in Supplementary Table S2. The average number of

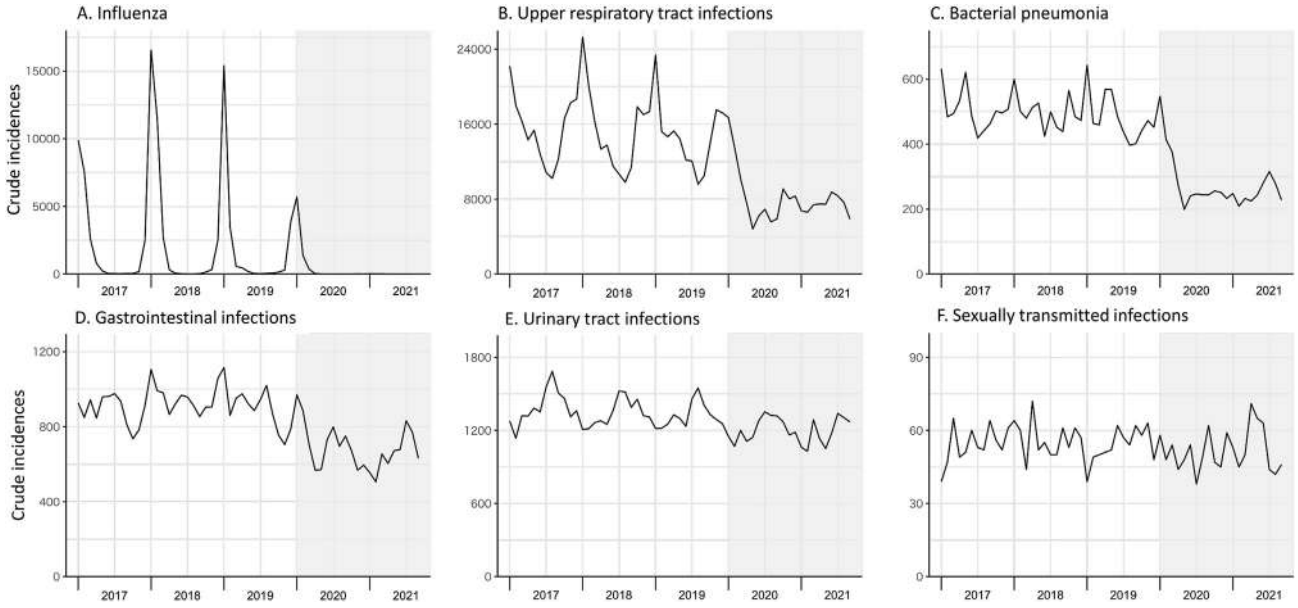

Fig. 1. Trends of monthly crude incidences for infectious diseases before the COVID-19 pandemic (from 2017 to 2019) and during the pandemic (from January 2020 to September 2021). (A) Influenza, (B) upper respiratory tract infections, (C) bacterial pneumonia, (D) gastrointestinal infections, (E) urinary tract infections and (F) sexually transmitted infections. The grey background represents the COVID-19 pandemic phase.

outpatient visits was 2,512 and 2,325 per 1,000 persons per month before and during the COVID-19 pandemic, respectively. The average healthcare costs were 38,299,000 and 37,365,000 Japanese yen (approximately 320,000 and 311,000 US dollars when converted to 120 yen to the dollar) per 1,000 persons per month before and during the COVID-19 pandemic periods, respectively.

The results of the adjusted IRRs of infectious diseases, number of outpatient visits and healthcare costs during the COVID-19 pandemic compared with the prepandemic period are presented in Table 1. A remarkable decrease (>94%) in influenza incidence was observed after April 2020. The incidence of URI and bacterial pneumonia also significantly decreased (by approximately 50%) from April 2020 to June 2021, although the adjusted IRRs slightly increased in July to September 2021. In contrast, the proportion of hospitalisations among all bacterial pneumonia episodes was significantly elevated from 25.1% before the COVID-19 pandemic to 29.3% during the pandemic (risk difference, 4.2% [95% confidence interval (CI), 2.6%–5.9%]; $P < 0.001$). The incidence of gastrointestinal infections and UTIs also decreased significantly (by approximately 30% and 10%, respectively) during the pandemic period. Meanwhile, the incidence of STIs did not decrease during the COVID-19 pandemic period, with a significant increase observed in April to June 2021 (adjusted IRR, 1.37 [95% CI, 1.18–1.60]). The trends in adjusted IRRs of STIs by gender for each quarter are shown in Supplementary Table S3. STIs incidence among women significantly increased in April to June 2021 (adjusted IRR, 1.41 [95% CI, 1.20–1.65]), which was not observed among men (adjusted IRR, 0.90 [95% CI, 0.47–1.72]).

The number of outpatient visits and healthcare costs also significantly decreased throughout the pandemic period; the adjusted IRRs of outpatient visits ranged from 0.86 to 0.93, and those of healthcare costs ranged from 0.91 to 0.97, respectively (Table 1).

Discussion

In this region-wide study using a patient-based claims database, a significant reduction in non–COVID-19 respiratory infections, acute gastroenteritis and UTIs was reported during the COVID-19 pandemic; however, an increase in STIs was observed. An indirect impact on the incidence of non–COVID-19 diseases has been reported in several countries. Kadambari et al. analysed trends in paediatric hospitalisations for 19 infectious diseases using data from all NHS hospitals in England.[11] The authors reported a 94%, 66%, 82% and 60% reduction in hospital admissions for influenza, URI, bronchiolitis and pneumonia, respectively. A 32% reduction in community-acquired pneumonia in people aged ≥65 years was observed in a region-wide study of individuals using the public healthcare system in Tuscany, Italy.[7] In Japan, Nagano et al. and Yan et al. reported a 50% decrease in the number of hospitalised patients with community-acquired pneumonia during the COVID-19 pandemic.[5,12] However, these previous studies were conducted using hospital databases and did not cover medical care provided in clinics, where most outpatients visit. The observed decreases in non–COVID-19 infectious diseases, including those seen in the present study, could be due to a reduction in the disease incidence or behavioural changes as part of stay-at-home mandates. This study observed a significantly greater reduction in non–COVID-19 respiratory infections, including influenza, URI and bacterial pneumonia, and gastrointestinal infections, compared with the number of outpatient visits. UTIs also decreased slightly, although the reduction rate was similar to that of outpatient visits. Therefore, the decline in the incidence of UTIs and the number of outpatient visits may have also impacted the rate of reported UTIs. The decline in the incidence of non–COVID-19 respiratory tract infections continued throughout the pandemic, including when the prevalence of COVID-19 cases was low and when the region was not in a declared state of emergency. Behavioural changes, including physical/social distancing, wearing masks and hygiene measurements, are likely to be the main reasons for this decline. In addition, the current claims-based study does not rule out the possibility that infectious diseases were underdiagnosed because people avoided visiting clinics or hospitals in association with stay-at-home recommendations.

The decrease in the incidences of gastrointestinal infections and UTIs, which showed a 10%–39% and 9%–13% reduction, respectively, in this study, were reported in several other studies.[8,9] In Germany, during the pandemic period (from April 2020 to March 2021), the number of patients with gastrointestinal infections and UTIs

Table 1
Adjusted incidence rate ratios (IRRs) and 95% confidence intervals of infectious diseases, outpatient visits and healthcare costs during every quarter of the COVID-19 pandemic period compared 2017–2019 (prepandemic period).

Infectious diseases, outpatient visits, healthcare costs	2020				2021		
	Jan.–Mar.	Apr.–Jun.	Jul.–Sep.	Oct.–Dec.	Jan.–Mar.	Apr.–Jun.	Jul.–Sep.
Influenza	0.34 (0.33–0.35)	0.06 (0.04–0.08)	0.05 (0.02–0.13)	0.00 (0.00–0.01)	0.00 (0.00–0.00)	0.01 (0.00–0.02)	0.06 (0.03–0.15)
Upper respiratory tract infections	0.72 (0.72–0.73)	0.46 (0.46–0.47)	0.58 (0.57–0.59)	0.51 (0.50–0.52)	0.39 (0.39–0.40)	0.61 (0.60–0.62)	0.73 (0.72–0.74)
Bacterial pneumonia	0.84 (0.79–0.89)	0.44 (0.41–0.48)	0.54 (0.50–0.58)	0.49 (0.46–0.53)	0.43 (0.40–0.47)	0.49 (0.45–0.53)	0.64 (0.60–0.69)
Gastrointestinal infections	0.90 (0.86–0.94)	0.67 (0.64–0.71)	0.82 (0.78–0.86)	0.73 (0.70–0.77)	0.61 (0.58–0.64)	0.75 (0.71–0.78)	0.85 (0.81–0.89)
Urinary tract infections	0.91 (0.88–0.95)	0.89 (0.85–0.92)	0.87 (0.84–0.90)	0.88 (0.85–0.92)	0.92 (0.89–0.96)	0.87 (0.83–0.90)	0.88 (0.85–0.91)
Sexually transmitted infections	1.13 (0.95–1.34)	0.94 (0.79–1.12)	0.96 (0.81–1.14)	0.95 (0.80–1.14)	1.13 (0.95–1.34)	1.37 (1.18–1.60)	0.90 (0.76–1.08)
Outpatient visits	0.93 (0.93–0.93)	0.86 (0.86–0.86)	0.90 (0.90–0.90)	0.89 (0.89–0.89)	0.90 (0.89–0.90)	0.91 (0.91–0.91)	0.91 (0.91–0.91)
Healthcare costs	0.97 (0.97–0.97)	0.91 (0.91–0.91)	0.94 (0.94–0.94)	0.93 (0.93–0.93)	0.96 (0.96–0.96)	0.96 (0.96–0.96)	0.95 (0.95–0.95)

COVID-19, coronavirus disease 2019

Adjusted IRRs 0.00–0.39 with significance
Adjusted IRRs 0.40–0.79 with significance
Adjusted IRRs 0.80–0.99 with significance
Adjusted IRRs ≥1.01 with significance
No significant difference

decreased by 36% and 11%, respectively, compared with the prepandemic period (from April 2019 to March 2020).[8] A study from Finland found that the incidence of cystitis among children was 11%–12% lower in 2020 than in 2017–2019.[9] Interestingly, the reduction rate of UTIs was similar to that in the present study, although measures of social restrictions and the scale of COVID-19 epidemics varied in different countries. UTIs have been considered non-communicable diseases; therefore, improved hygiene measurements during the pandemic may have also contributed to the reduction in occurrence.[9]

In this study, the IRRs of STIs (syphilis, chlamydia and gonococcal infections combined with diagnostic tests) did not decrease in 2020 and increased significantly in April to June 2021. The indirect impact of COVID-19 on the incidence of STIs has also been reported in the United States. Kelly et al. reported a decrease in the number of reported cases of chlamydial diseases (31%), late syphilis (19%), early syphilis (15%) and gonorrhoea (13%) during January to June 2020 compared with January to June 2019 using California surveillance data.[13] In this report, delays in diagnosis and treatment were a concern. It was stated that urgent interventions by healthcare providers and public health officers were needed to help mitigate the pandemic's negative consequences on STI control. In the Japanese national surveillance system, the number of diagnoses of syphilis decreased in 2020 (3,046 cases) compared with 2019 (3,753 cases); however, it increased in 2021 (4,497 cases).[14] There are several hypotheses about the potential factors associated with the increase in STIs during the COVID-19 pandemic. According to the US Center for Disease Control and Prevention,[15] (1) more people may seek screening or care after lifting restrictions; (2) people with STIs may transmit the infection to others for longer periods because of the reduced access to health care; and (3) social restriction measures may have changed the sexual behaviour of individuals, including an increase in new sexual partners or networks.

The present study also showed a gender difference in the trend of incidence of STIs. However, there is concern that STIs may be underdiagnosed, particularly in men compared with women. It is suggested that chlamydial infection, which is the most common STI and often has little or no symptoms in men, is one of the pivotal factors. Underdiagnosis or underreporting of chlamydia may be due to decreased screening during the pandemic.[15,16] This may be a serious public health concern, and appropriate screening and medical consultations are strongly recommended. Health promotion strategies and warnings aimed at the public and healthcare providers are also needed.

This study evaluated the number of outpatient visits and healthcare costs. Throughout the pandemic period, the decline in healthcare costs was marginal (3%–9%) compared with the decline in outpatient visits (7%–14%). These results are consistent with a previous study that reported a 6.3% decrease in Japanese acute care hospital charges in April and May 2020 (the first wave of the pandemic).[17] The present study revealed that the declines in outpatient visits and healthcare costs continued through to September 2021 (the end of the fifth wave). The reported number of non-infectious diseases, such as malignant tumours, decreased during the pandemic, and treatment for malignancies was delayed due to the depletion of medical resources in association with the COVID-19 pandemic.[18,19] In the present study, an approximately 20% decrease in the number of surgeries for gastrointestinal cancers was observed during the COVID-19 pandemic when the state of emergency or quasi-emergency measures were implemented (data not shown).

Several studies have described the indirect impact of COVID-19 on healthcare utilisation.[20,21] Recently, Perofsky et al. reported a substantial decline in hospitalisations and emergency department visits unrelated to COVID-19.[20] The authors were concerned about the delay in seeking care among high-risk patients and potential future increases in morbidity or mortality. STIs were the greatest concern in this study; screening, diagnosis and treatment need to be provided extensively to prevent further transmission, even if patients have mild or no symptoms or if people are under social restrictions from the public health perspective.

The strength of the present study is its large, population-based data set covering 800,000 residents. Various infectious diseases were evaluated simultaneously, focusing on the difference between non–COVID-19 infections and STIs; it was observed that the COVID-19 pandemic impacted different diseases to a varying extent.

The present study also has several limitations. First, the results may not be representative of the whole of Japan because the claims database used in this study was composed of claims from only one prefecture. Second, because an administrative claims database was used, the accuracy of the diagnosis was not validated. However, changes and trends were considered possible to evaluate because the recording of the diagnosis, testing and treatment behaviour of healthcare providers probably did not change. Third, only the incidence of disease was evaluated; therefore, data regarding disease severity or mortality were not included in the present analysis. Finally, although several cofactors may exist between the COVID-19 pandemic and the incidence of non–COVID-19 illnesses, this study could not assess the magnitude of the effect of each mediator, such as social restrictions, physical distancing and hygiene measures.

In conclusion, this patient-based claims database study revealed that the incidence of non–COVID-19 respiratory tract and gastrointestinal infections dramatically decreased during the COVID-19 pandemic. UTIs also decreased slightly, whereas STIs did not decrease, but rather increased, and large STI epidemics are of concern. Despite behavioural restrictions and changes due to the COVID-19 pandemic, there remains a need for appropriate and continued STI screening and promotion of care-seeking behaviours among at-risk individuals.

Author statements

Ethical approval

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Jichi Medical University Hospital (approval number 21-198).

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Competing interests

None declared.

Authors' contributions

N.K., H.H., T.I. and S.H. designed the study. N.K., Y.H., K.G. and N.M. collected, organised and analysed the data and performed statistical analyses. N.K., H.H. and S.H. interpreted data. N.K. and S.H. drafted the article. All the authors critically revised the article for intellectual content. All authors have read and approved the final article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.10.018.

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Themed Paper – Original Research

Inequality of handwashing practice using antimicrobial agents in Bangladesh: a household level analyses

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ABSTRACT

Objectives: About 2.3 billion individuals worldwide are still deprived of the amenity of handwashing with antimicrobial agents. The progress of handwashing with antimicrobial agents in Bangladesh is relatively slower than in many developing countries. The objective of this study was to capture the inequality of the prevalence of handwashing with antimicrobial agents and to identify the factors that are potentially contributing to socio-economic inequalities of handwashing practice in Bangladesh.
Study design: Cross-sectional study.
Methods: The present study used the nationally representative cross-sectional data from the latest Bangladesh Demographic and Health Survey (BDHS) 2017–18. A total of 19,457 households were included in the analysis of this study. A regression-based decomposition method was applied to assess the socio-economic contributors of inequality.
Results: This study showed that only 38% of Bangladeshi households wash their hands with antimicrobial agents while a pro-rich socio-economic inequality was observed. Household's wealth index was responsible for about 46% of the overall inequality of handwashing with antimicrobial agents while the type of place for handwashing variable contributed 38% of total inequalities. Hygienic toilet facilities (12%) and exposure to mass media (7.4%) are other determinants of total inequalities of handwashing with antimicrobial agents.
Conclusions: Despite recent declines in attributable mortality, handwashing with antimicrobial agents remains an important determinant of public health problems in many developing countries like Bangladesh. The regular programs aimed at promoting best hand hygiene practices and ensuring the availability of the necessary infrastructure at the community level will be important measures to eliminate this inequality at the population level.

Introduction

Handwashing with soap and water is the base of public health and has been considered a measure of personal hygiene for centuries as the most effective way to halt the transmission of various infectious diseases as well as healthcare-associated pathogens.[1,2] Although public health organizations have purposefully and persistently promoted the necessity of handwashing for a very long time, the recent pandemic of coronavirus disease 2019 (COVID-19) infection has put a spotlight on its practice with antimicrobials for the efficacious 'flatten the epidemiological curve' outcome.[3] However, about 2.3 billion individuals worldwide are still denied the amenity to wash their hands with soap and water at home.[4] It is estimated that over 700 children die every day due to the diseases associated with unsafe water, and poor hygiene practices.[5] It is well documented and established that good hand hygiene practice can lower mortality rates from respiratory and diarrheal infections in children younger than 5 years by up to 21% and 30%, respectively.[4]

Hand hygiene with antimicrobial agents is vital to prevent the spread of all infectious disease outbreaks, including COVID-19. One must wash their hands after using the restroom, before eating, and after touching something drossy to prevent the spread of numerous germs.[6] According to the epidemiological evidence, hands are known to carry and transmit bacterial and viral respiratory pathogens, which microbiologists have detected in hands.[7] The majority of bacteria and microorganisms that come into touch with hands

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are slow to colonize and can be quickly removed by washing hands with antimicrobial soaps.[8] Therefore, using soap and other antimicrobial agents during handwashing, especially during times of public health significance—after contact with excrement and before handling food—can stop the spread of numerous infectious diseases, including skin infections and trachoma.[9] Although handwashing with antimicrobial agents is a cost-effective intervention for preventing various infectious diseases for a long time, it has been neglected for showy and advertise alternatives.[10] However, it is estimated that one in every four persons does not have access to a handwashing facility with soap and water globally; whereas only 26% of potential fecal contacts are followed by handwashing with soap.[11]

Bangladesh, a lower-middle-income country (LMIC), has made remarkable progress in many health indicators in recent years. In line with the other health indicators, the country has increased the coverage of populations with basic hygiene services at the household level. However, progress towards universal basic hygiene in Bangladesh is relatively slower than in many developing countries.[4] In recent years, handwashing promotion has become a compelling and increasing priority for governments and non-governmental organizations in Bangladesh.[12] In the year 2020, Bangladesh was one of the first LMICs to accelerate the development of a national hygiene roadmap and adopted both short- and long-term strategies for hand hygiene as a pillar of public health in line with the Sustainable Development Goal (SDG) six calls for the global community to achieve access to hygiene for all by 2030.[4] Irrespective of these initiatives, the practice of handwashing with antimicrobial agents is very low in Bangladesh.[13] Handwashing practice is strongly associated with cultural norms, where people of all ages learn in accordance with their diverse religious and cultural backgrounds.[14]

Although handwashing with soap and other antimicrobial agents is the best way to keep families safe and healthy, a larger number of Bangladeshi households are still left out of the benefits achieved by low-cost intervention.[15] A study indicated that the presence of water sources and water body in close proximity to the household doubles the probability of handwashing in Bangladesh.[16] Indeed, access to water and soap is essential to improve the handwashing practice, which is often limited in many households in Bangladesh.[17] It was also observed that handwashing place in the households with water and soap is the best indicator for frequent handwashing in both rural and urban households[18] A systematic review study indicated that the potential determinants of handwashing were education, wealth, gender, risk of diseases, knowledge, and handwashing infrastructures.[19] A study focusing on rural Bangladesh observed that handwashing with antimicrobial agents was more common among mothers compared to the other members of the household and mothers from the richest households used antimicrobial agents more than the poorest segment of the society.[20] Various studies observed that household heads with higher educational degrees often had a higher attitude toward handwashing with antimicrobial agents.[21,22] Indeed, handwashing practices have often been shaped by culturally learned patterns.[23] Another study indicated that designated handwashing places containing soap and water were the most contributing factors to handwashing inequalities; as such opportunities increase the rate of handwashing.[24] However, there is a dearth of literature focusing on the persistent inequality of handwashing with antimicrobial agents at household level, particularly in the context of Bangladesh. The objective of this study is to capture the inequality caused by the prevalence of handwashing with antimicrobial agents and to identify the factors that are potentially contributing to socio-economic inequalities in Bangladesh. The study also tried to assess the possible factors that may influence handwashing behavior using the latest demography and survey data. The findings of this study can inform and play a role in investment decisions on hand hygiene practice in Bangladesh and elsewhere with similar socio-economic conditions.

Methods

Data and study population

The present study used nationally representative cross-sectional data from the latest Bangladesh Demographic and Health Survey (BDHS) 2017–18. Bangladesh is located in the northeastern part of South Asia, a country with 164 million inhabitants. The country has recently been upgraded to an LMIC as per the World Bank's classification. Bangladesh is on track to achieve the United Nations' Sustainable Development Goals (SDGs) by 2030, particularly in poverty reduction, gender equality, electricity, sanitation, and annual GDP growth. The survey was implemented from October 2017 to March 2018, under the National Institute of Population Research and Training (NIPORT) of the Ministry of Health and Family Welfare. The survey design adopted a two-stage stratified cluster sampling frame to select the households. In the first stage, the survey selected 675 enumeration areas (EAs) and conducted household listing for each EA in both rural and urban areas. In the second stage, an average of 30 households were selected systematically from each EA. The detailed sampling and data collection procedure has been described elsewhere.[25] A structured questionnaire was administered by trained and experienced interviewers. A total of 19,457 participants were analyzed for this study. The survey was approved by the institutional review board of MEASURE DHS and the National Research Ethics Committee of the Bangladesh Medical Research Council. As per their procedure, informed consent was obtained from all participants.

Variables

The outcome variable of this study was handwashing with water and soap or with various antimicrobial agents (such as detergents, powder, and liquid handwash). The respondents were asked what they usually use to wash their hands. If they reported to wash hands with soap or any other antimicrobial agents, then they were regarded as performing handwashing with antimicrobial agents.

Major explanatory variables comprised the age of the household heads (less than 31 years, 31–50 years, 51–65 years, 65+ years), sex of the household heads (male, female), household heads highest educational level (no formal education, primary, secondary, higher), women's highest educational level (no formal education, primary, secondary, higher), size of the household (less than three members, 3–4 members, 5–6 members, 7 or above members), mass media exposure (have access, no access), drinking water sources (improved/unimproved), type of place for handwashing (covered space, shared open space, unshared open space), hygienic toilet facilities (yes/no), toilet sharing status (yes/no), administrative division (Dhaka, Chattogram, Rajshahi, Rangpur, Khulna, Sylhet, Barisal, Mymensingh), and wealth index of the households. Places of residence were indicated as urban and rural. The socio-economic status of household members was measured by calculating the wealth index using principal component analysis, resulting in categorization into the 'poorest', 'poorer', 'middle', 'richer', and 'richest' quintiles as per the DHS guideline.[25]

Statistical analysis

Data were analyzed using STATA V.16.0 (StataCorp LP) for descriptive analysis and multivariable logistic regression.

Descriptive bivariate analysis was performed using cross tables and chi-squared tests to explore the determinants and the prevalence of handwashing using antimicrobial agents and the results were interpreted as statistically significant at a *P*-value of <0.05. The adjusted odds ratios (AOR) and 95% confidence interval (CI) were also reported by using multivariable logistic regression approach. Variance inflation factor test was used to detect the multicollinearity in the regression model. For inequality analysis, we have plotted the concentration curve, assessed the concentration indices (CIs), and decomposed the concentration index of handwashing with antimicrobial agents. The concentration curve showed the pattern and degree of discriminations of handwashing with antimicrobial agents across the socio-economic strata. The status of the concentration curve may lie above or below the equality line, which indicates that the status of handwashing using antimicrobial agents is more concentrated among the poor (lowest) and among the rich (highest) segment of the population, respectively. Secondly, the concentration indexes (CIs) were calculated using the standard method developed by Kakwani et al.[26] Concentration indexes summarize the graphical information (i.e., the area between the equality line and the concentration curve) generated by a concentration curve. The CI abridges the data contained in each concentration curves, and is twice the area between concentration curves and the line of equality. A convenient simple computational formula for the concentration index can be written as follows:

$$CI = \frac{2}{\mu} COV(h, r)$$

where CI = concentration index; μ represents the (weighted) mean of the handwashing status with antimicrobial agents; h is handwashing with antimicrobial agents; r represents the fractional rank of the individual in the distribution of wealth index, and *cov* indicates the weighted covariance between h and r. The value of the concentration index ranges from −1 to +1, where a negative index value is equivalent to a pro-poor concentration curve and a positive index corresponds to a pro-rich concentration curve. Moreover, a concentration index value of zero implies that there is no inequality for handwashing with antimicrobial agents across people from different socio-economic statuses.

Finally, to identify the contribution of various socio-economic factors to the inequality, a regression-based decomposition analysis was used.[27] For these purposes, the regression model for the health outcome Y (handwashing with antimicrobial agents) with the set of k determinants (X_k) can be written as follows:

$$Y = \alpha + \sum_k \beta_k X_k + \varepsilon$$

where X_k represents the selected explanatory (socio-economic) variables, β_k is the coefficient of X_k, and ε is the stochastic error term. The CI for handwashing with antimicrobial agents from the above regression (Y) can be decomposed as follows:

$$CI = \sum_k (\beta_k \overline{X}_k / \mu) \Big/ C_k + GC_\varepsilon \Big/ \mu$$

Here, CI is the concentration index; μ represents the mean of handwashing with antimicrobial agents (Y); $\overline{X}_k$ is the average of Kth socio-economic variable(s), i.e., X_k; C_k represents the concentration index of X_k, and GC_ε is the generalised concentration of the error term (ε); $\frac{\beta_k \overline{X}_k}{\mu}$ implies the elasticity of the prevalence of handwashing with antimicrobial agents with respect to the explanatory variable. Here, GC_ε/μ is the residual component that denotes the part of income-induced inequality in handwashing with antimicrobial agents that cannot be explained by the explanatory variables. The findings from the decomposition approach were presented in elasticity, concentration index value, absolute contribution (same unit as the concentration index), and the percentage (relative) contribution.

Results

Background characteristics

The background characteristics of the study participants and handwashing behaviors are displayed in Table 1. A total of 19,457 households were included in the analysis of this study. Around 50% of the household heads were aged 31–50 years and the proportion of males and females was 84% and 16%, respectively. Regarding educational level, 33% of household heads had primary education, followed by no education (29%), whereas only 12% had higher educational attainment. We observed that only 11% of women had higher education while most of them completed secondary (38%) and primary education (33%). Most of the households consisted of 3–4 members (45%) followed by larger households (30%). More than half (52%) of the households had no exposure to the mass media. Almost all the households (98%) had improved sources of drinking water. About 39% of households had used open and shared space for washing their hands while another 29% of households used open space but not shared with other households. About 32% of households used covered space for handwashing. Moreover, in the case of toilet facilities, most of the households (69%) used hygienic toilet facilities while 35% of households shared their toilet with other households.

Prevalence of handwashing using antimicrobial agents

The prevalence of handwashing using antimicrobial agents across sociodemographic variables is described in Table 2. We observed that about 38% of total households used antimicrobial agents during washing hands. The urban households used antimicrobial agents more (56%) compared to the rural households (31%). The prevalence of handwashing was found to be higher among the household heads aged from 51 up to 65 years (40%). Male-headed households used slightly higher (38%) than female-headed households (36%). Handwashing using antimicrobial agents was more frequent in households with higher educated heads (72%) and it was also pretty common in presence of higher educated women (72%) in that particular household. The utilization of antimicrobial agents was higher among households who had access to mass media (55%), improved water source (38%), hygienic toilet facilities (48%), covered handwashing places (72%), and not shared their toilet with others (46%). According to the administrative divisions, the prevalence of handwashing was highest in Dhaka regions (47%) followed by Chattogram (40%). It was found that households from the richest households from urban (84%) and rural (83%) had more handwashing practice, whereas only 10% of the poorest households used antimicrobial agents for washing their hands.

Factors associated with handwashing using antimicrobial agents

Factors that are closely related with handwashing using antimicrobial agents are described in Table 3. We observed that the age of the household heads had a significant positive relationship with handwashing using antimicrobial agents. Household head in each of the categories of age 31–50 years had 1.23 (95% CI: 1.03, 1.45) times and 51–65 years had 1.25 (95% CI: 1.04, 1.49) times higher odds of using antimicrobial agents during handwashing, compared

Table 1
Background characteristics of the study participant ($N = 19,457$).

Variables	Urban ($n = 5505$)		Rural ($n = 13,952$)		Overall ($n = 19,457$)	
	N	%	*N*	%	*N*	%
Age of the household head (years)						
<31	1080	19.61	2241	16.06	3321	17.07
31–50	2963	53.82	6849	49.09	9812	50.43
51–65	1121	20.36	3382	24.24	4503	23.14
65+	342	6.21	1479	10.60	1821	9.36
Sex of the household head						
Male	4775	86.73	11,598	83.13	16,373	84.15
Female	730	13.27	2354	16.87	3084	15.85
Highest educational level of the household head						
No formal education	1199	21.78	4424	31.71	5623	28.90
Primary education	1602	29.11	4821	34.55	6423	33.01
Secondary education	1546	28.08	3485	24.98	5031	25.86
Higher education	1158	21.03	1222	8.76	2380	12.23
Highest educational level of women						
No formal education	780	15.34	2440	19.62	3220	18.38
Primary education	1485	29.20	4344	34.93	5829	33.27
Secondary education	1922	37.79	4692	37.73	6614	37.75
Higher education	899	17.67	959	7.71	1858	10.60
Households size						
<3 members	694	12.60	1566	11.23	2260	11.62
3–4 members	2572	46.72	6078	43.56	8650	44.46
5–6 members	1610	29.25	4299	30.81	5909	30.37
7 or above members	629	11.43	2009	14.40	2638	13.56
Mass media exposure (radio/television)						
Have access	3859	70.10	5422	38.86	9281	47.70
No access	1646	29.90	8530	61.14	10,176	52.30
Sources of drinking water						
Improved	5472	99.39	13,663	97.93	19,135	98.34
Unimproved	33	0.61	289	2.07	322	1.66
Type of place for handwashing						
Covered space	2837	51.53	3387	24.28	6224	31.99
Unshared open space	870	15.80	4750	34.05	5620	28.88
Shared open space	1798	32.67	5814	41.68	7613	39.13
Hygienic toilet facilities						
Yes	4781	86.84	8665	62.11	13,446	69.11
No	725	13.16	5286	37.89	6011	30.89
Sharing of toilet						
Yes	2339	42.48	4483	32.13	6821	35.06
No	3167	57.52	9469	67.87	12,636	64.94
Division						
Dhaka	2557	46.44	2385	17.10	4942	25.40
Chattogram	919	16.70	2382	17.07	3301	16.96
Rajshahi	561	10.18	2225	15.95	2786	14.32
Rangpur	339	6.17	2037	14.60	2376	12.21
Khulna	492	8.93	1761	12.62	2253	11.58
Sylhet	199	3.62	913	6.54	1112	5.72
Barisal	182	3.31	908	6.51	1090	5.60
Mymensingh	256	4.66	1341	9.61	1597	8.21
Wealth index						
Poorest	387	7.04	3662	26.25	4050	20.81
Poorer	380	6.91	3579	25.65	3960	20.35
Middle	654	11.87	3150	22.58	3803	19.55
Richer	1579	28.69	2301	16.49	3880	19.94
Richest	2505	45.50	1259	9.03	3764	19.35
Total	5505	28.29	13,952	71.71	19,457	100.00

to household head aged less than 31 years ($P < 0.01$). Higher education of the household heads had a significant positive association with the use of antimicrobial agents for handwashing. If the household heads had a higher education, the households were 1.47 (95% CI: 1.23, 1.74) times more likely to use antimicrobial agents than uneducated household heads, and was statistically significant ($P < 0.001$). The similar pattern was also observed among the presence of higher educated women in the particular households (AOR = 1.91; 95% CI: 1.58–2.32, $P < 0.001$) compared to households with women who had no formal education.

It was found that households with 3–4 members were 1.22 times more likely to washing hands using antimicrobial agents (95% CI: 1.03, 1.44, $P < 0.01$), compared to households with less than three members. The similar patterns were visible in households with more than seven members (AOR = 1.22; 95% CI: 1.01–1.48, $P < 0.05$). Those who used open space for handwashing and used unimproved drinking water (AOR = 0.37; 95% CI: 0.22–0.61, $P < 0.001$) were less likely to use antimicrobial agents for handwashing. The odds of unshared open space (AOR = 0.34; 95% CI: 0.31–0.38, $P < 0.001$) and shared open space (AOR = 0.14; 95% CI: 0.13–0.16, $P < 0.001$) were significantly lower than the households that had covered space for handwashing. The exposure to mass media (AOR = 1.19; 95% CI: 1.08–1.31, $P < 0.001$) and having hygienic toilet facilities (AOR = 1.46; 95% CI: 1.31–1.62, $P < 0.001$)

Table 2
Prevalence of handwashing using antimicrobial agents across sociodemographic variables.

Variables	Urban ($n = 3063$)		Rural ($n = 4254$)		Overall ($N = 7318$)	
	N	%	*N*	%	*N*	%
Age of the household head (years)						
<31	483	44.73	553	24.68	1036	31.20
31–50	1708	57.63	2155	31.47	3863	39.37
51–65	685	61.11	1116	32.99	1801	39.99
65+	188	54.97	430	29.07	618	33.93
P-value	*<0.001*		*<0.001*		*<0.001*	
Sex of the household head						
Male	2694	56.42	3521	30.36	6216	37.96
Female	369	50.52	733	31.15	1102	35.74
P-value	*0.003*		*0.343*		*0.016*	
Highest educational level of the household head						
No formal education	415	34.57	877	19.83	1292	22.97
Primary education	667	41.61	1309	27.16	1976	30.77
Secondary education	968	62.61	1363	39.10	2331	46.33
Higher education	1014	87.56	705	57.71	1719	72.24
P-value	*<0.001*		*<0.001*		*<0.001*	
Highest educational level of women						
No formal education	269	34.46	477	19.55	746	23.16
Primary education	605	40.76	1127	25.94	1732	29.72
Secondary education	1194	62.11	1753	37.37	2947	44.56
Higher education	786	87.43	551	57.48	1337	71.97
P-value	*<0.001*		*<0.001*		*<0.001*	
Households size						
<3 members	304	43.81	389	24.85	693	30.67
3–4 members	1428	55.50	1837	30.23	3265	37.74
5–6 members	943	58.54	1301	30.27	2244	37.97
7 or above members	389	61.83	727	36.18	1116	42.30
P-value	*<0.001*		*<0.001*		*<0.001*	
Mass media exposure (radio/television)						
Have access	2565	66.48	2554	47.11	5120	55.17
No access	498	30.24	1700	19.93	2198	21.60
P-value	*<0.001*		*<0.001*		*<0.001*	
Sources of drinking water						
Improved	3059	55.90	4235	31.00	7294	38.12
Unimproved	4	13.35	19	6.64	24	7.34
P-value	*<0.001*		*<0.001*		*<0.001*	
Type of place for handwashing						
Covered space	2319	81.74	2172	64.13	4491	72.16
Unshared open space	380	43.67	1466	30.87	1846	32.85
Shared open space	364	20.25	616	10.60	980	12.88
P-value	*<0.001*		*<0.001*		*<0.001*	
Hygienic toilet facilities						
Yes	2928	61.24	3503	40.42	6431	47.83
No	136	18.71	751	14.21	887	14.76
P-value	*<0.001*		*<0.001*		*<0.001*	
Sharing of toilet						
Yes	746	31.89	818	18.26	1564	22.93
No	2317	73.18	3436	36.29	5753	45.53
P-value	*<0.001*		*<0.001*		*<0.001*	
Division						
Dhaka	1512	59.14	826	34.64	2338	47.32
Chattogram	474	51.60	853	35.84	1328	40.23
Rajshahi	311	55.46	765	34.37	1076	38.62
Rangpur	211	62.26	706	34.66	917	38.61
Khulna	244	49.54	496	28.14	739	32.81
Sylhet	98	49.26	226	24.76	324	29.15
Barisal	77	42.48	108	11.90	185	17.01
Mymensingh	135	52.83	274	20.44	410	25.64
P-value	*<0.001*		*<0.001*		*<0.001*	
Wealth index						
Poorest	45	11.49	360	9.84	405	9.99
Poorer	72	18.85	644	17.99	715	18.07
Middle	197	30.12	1033	32.80	1230	32.34
Richer	641	40.62	1173	50.95	1814	46.75
Richest	2109	84.19	1045	82.94	3153	83.77
P-value	*<0.001*		*<0.001*		*<0.001*	
Total	3063	55.64	4254	30.49	7318	37.61

Table 3
Factors associated with handwashing in Bangladesh.

Variables	Unadjusted	Adjusted
	OR (95% CI)	OR (95% CI)
Age of the household head (years)		
<31	0.88* (0.78, 1.00)	1.00 (0.82, 1.22)
31–50	1.26*** (1.14, 1.40)	1.23** (1.03, 1.45)
51–65	1.30*** (1.16, 1.45)	1.25** (1.04, 1.49)
65+ (ref.)		
Sex of the household head		
Male (ref.)		
Female	0.91** (0.84, 0.98)	1.05 (0.94, 1.18)
Highest educational level of the household head		
No formal education (ref.)		
Primary education	1.49*** (1.37, 1.62)	1.17** (1.04, 1.30)
Secondary education	2.89*** (2.66, 3.15)	1.32*** (1.16, 1.49)
Higher education	8.73*** (7.82, 9.73)	1.47*** (1.23, 1.74)
Highest educational level of women		
No formal education (ref.)		
Primary education	1.40*** (1.27, 1.55)	1.18** (1.04, 1.34)
Secondary education	2.67*** (2.42, 2.93)	1.46*** (1.28, 1.67)
Higher education	8.52*** (7.48, 9.70)	1.91*** (1.58, 2.32)
Households size		
<3 members (ref.)		
3–4 members	1.37*** (1.24, 1.51)	1.22** (1.03, 1.44)
5–6 members	1.38*** (1.25, 1.54)	1.11 (0.94, 1.33)
7 or above members	1.66*** (1.47, 1.87)	1.22* (1.01, 1.48)
Type of place for handwashing		
Covered space (ref.)		
Unshared open space	0.19*** (0.17, 0.20)	0.34*** (0.31, 0.38)
Shared open space	0.06*** (0.05, 0.06)	0.14*** (0.13, 0.16)
Mass media exposure (radio/television)		
Have access	4.47*** (4.20, 4.75)	1.19*** (1.08, 1.31)
No access (ref.)		
Sources of drinking water		
Improved (ref.)		
Unimproved	0.13*** (0.08, 0.20)	0.37*** (0.22, 0.61)
Hygienic toilet facilities		
Yes	5.30*** (4.89, 5.73)	1.46*** (1.31, 1.62)
No (ref.)		
Sharing of toilet		
Yes (ref.)		
No	2.81*** (2.63, 3.00)	2.05*** (1.85, 2.27)
Place of residence		
Urban	2.86*** (2.68, 3.05)	1.09 (0.98, 1.21)
Rural (ref.)		
Division		
Dhaka	2.18*** (1.90, 2.51)	1.45*** (1.18, 1.77)
Chattogram	1.64*** (1.41, 1.89)	1.22 (0.99, 1.50)
Rajshahi	1.53*** (1.32, 1.78)	1.75*** (1.41, 2.18)
Rangpur	1.53*** (1.31, 1.78)	2.23*** (1.79, 2.78)
Khulna	1.19* (1.02, 1.39)	1.17 (0.94, 1.46)
Sylhet (ref.)		
Barisal	0.50*** (0.41, 0.61)	0.62*** (0.47, 0.82)
Mymensingh	0.84* (0.71, 0.99)	1.07 (0.84, 1.36)
Wealth index		
Poorest (ref.)		
Poorer	1.99*** (1.74, 2.26)	1.67*** (1.43, 1.95)
Middle	4.31*** (3.81, 4.87)	2.77*** (2.35, 3.26)
Richer	7.91*** (7.01, 8.92)	4.37*** (3.67, 5.21)
Richest	46.49*** (40.65, 53.18)	12.54*** (10.18, 15.43)
Constant		0.07*** (0.05, 0.10)
N		17,468
LR chi2 (32)		8157.52
Prob > chi2		<0.001
Log-likelihood		−7606.33
Pseudo R2		0.3491
Mean VIF		3.23

CI, confidence interval; OR, odds ratio; VIF, variance inflation factor.

were significantly associated with handwashing with antimicrobial agents. We also observed a significant association among the administrative divisions and handwashing using antimicrobial agents. Those who lived in Dhaka, Rajshahi, and Rangpur divisions were 1.45 (95% CI: 1.18–1.77, $P < 0.001$), 1.75 (95% CI: 1.41–2.18, $P < 0.001$), and 2.23 (95% CI: 1.79–2.78, $P < 0.001$) times higher to use antimicrobial agents for handwashing, respectively, than the inhabitants who lived in Sylhet divisions while the households belonged to the Barisal division were less likely to use antimicrobial agents during handwashing (AOR = 0.62; 95% CI: 0.47–0.82, $P < 0.001$). As expected, the wealthiest households were most likely to use antimicrobial agents for handwashing compared to the poorest households. For instance, households from the richest and richer wealth quintiles were 12.54 (95% CI: 10.18–15.43, $P < 0.001$) and 4.37 (95% CI: 3.67–5.21, $P < 0.001$) times more likely to use antimicrobial agents while washing their hands particularly than the poorest households. The similar pattern was also observed among middle (AOR = 2.77, 95% CI: 2.35–3.26) and poorer (AOR = 1.67, 95% CI: 1.43–1.95) wealth quintiles and were statistically significant ($P < 0.001$).

Inequality in the prevalence of handwashing behavior

We estimated the concentration index and concentration curve to represent the inequality in the use of antimicrobial agents for handwashing (Fig. 1). We found that the concentration curve lies below the line of equality line (45° line), and the value of the CIs was 0.597 ($P < 0.001$) Therefore, this study found a pro-rich socio-economic inequality existed in the prevalence of handwashing using antimicrobial agents.

Decomposition of concentration index for handwashing behavior

The contribution of various socio-economic and demographic factors to inequalities in handwashing with antimicrobial agents are shown in Table 4. The column 'Elasticity' shows the change (positive or negative sign in elasticity indicates an increasing or decreasing change) in the dependent variables' association with a one-unit change in the explanatory variables. The positive or negative sign of the CI indicates that the factors were more concentrated among the rich or poor households, respectively. The percentage contribution embodies the relative contribution of each determinant included in the model to the overall inequality of handwashing with antimicrobial agents, while the positive and negative sign indicates the increasing or decreasing of the observed inequality, respectively. Household wealth index was responsible for about 47% of the overall inequality of handwashing with antimicrobial agents while the place of handwashing variables contributed 38% of the total inequalities. Hygienic toilet facilities (12%) and exposure to mass media (7.4%) were other determinants of total inequalities of handwashing with antimicrobial agents.

Discussion

This study demonstrated the prevalence of handwashing with antimicrobial agents, associated factors, and documented the utilization-related inequalities among Bangladeshi households. Hand hygiene is recognized as an efficacious public health behavior in the prevention of the infections of the respiratory tract, gastro-intestinal tract, and skin and soft tissue related infections.[28–30] A previous study in Bangladesh also found that handwashing with antimicrobial agents is effective for reducing etiological agents of diseases.[31] The present study found that less than half of the households used antimicrobial agents during handwashing, whereas the urban households (55%) used more microbial agents than rural households (30%). Furthermore, we observed a pro-rich socio-economic inequality in the utilization of antimicrobial agents during handwashing among Bangladeshi households.

It is a well-known fact that basic sanitation and proper personal hygiene practices can completely prevent infectious diseases.[32]

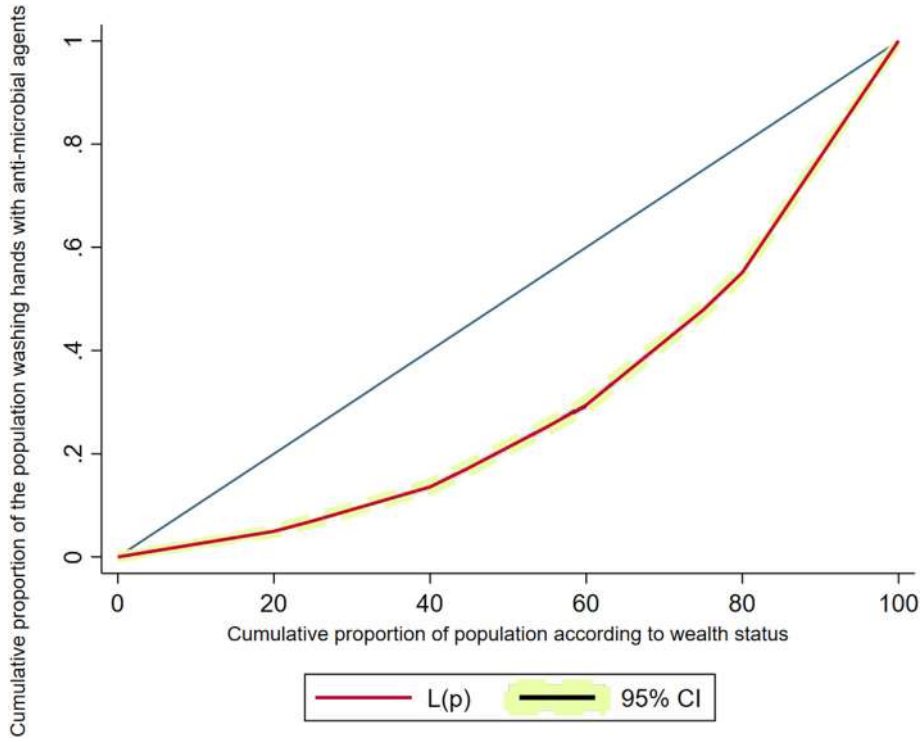

Fig. 1. Inequality in the prevalence of handwashing in Bangladesh.

However, only 38% of the households practiced handwashing in Bangladesh with antimicrobial agents, which is inadequate for tackling infectious diseases in Bangladesh. A recent study conducted in the urban regions of Bangladesh observed that over half of city dwellers still do not use antimicrobial agents when washing their hands, indicating that the majority of people are at risk of numerous infectious diseases and have suffered previously.[33] Our finding was similar to the earlier study where we found the prevalence of handwashing with antimicrobial agents is very low and people often preferred washing their hands only with water in rural areas of Bangladesh[34] We observed that various factors such as increasing age of the household heads, educational status, place of handwashing, mass media exposure, hygienic toilet facilities, administrative division, and wealth status were significantly associated with handwashing practiced with antimicrobial agents in Bangladesh.

Our study indicated that household heads aged 31 years and older are mostly concerned about the practice of using antimicrobial agents as they may have a better understanding about the benefits of handwashing, which would essentially prevent his/her households from various infectious diseases.[35] The older people generally preferred to use soap more for mental clarity or a physical sense of cleanliness, which also protected them from numerous health concerns.[23] In line with other studies, we found that handwashing practices were more common among the higher-educated individuals and those who belong to the wealthiest households.[36,37] In a study conducted in the rural Bangladesh regions, it was observed that socio-economic status was associated with better sanitation practices and use of the antimicrobial agents for handwashing practices.[34] Moreover, antimicrobial handwashing soaps were used by individuals who did not share a bathroom and had improved toilet facilities. Parallel to the result of earlier study, we also observed a wide variation of handwashing practices across Bangladesh in terms of administrative divisions.[38] Those who lived in Dhaka and Chattogram divisions used antimicrobial agents during handwashing more than their counterparts. The wealthiest households are mostly located in Dhaka and Chattogram; the two largest cities of Bangladesh. Dhaka is the capital city of Bangladesh; therefore, the average household income is comparatively larger than its counterparts and households spend more for their own health protections. In contrast, the Barisal division is frequently affected by natural disasters such as cyclones, extreme weather, river erosion, and waterlogging where more people live below the poverty.[39,40] The prevalence of handwashing using antimicrobial agents is lowest in Barisal among all the divisions of Bangladesh.

This study documented a pro-rich socio-economic inequality when it comes to the utilization of antimicrobial agents while washing hands. It was observed that the household wealth index is responsible for about 47% of the overall inequality. The wealthiest households have the means to afford to purchase more types of antimicrobial agents including soap than the poor households due to the affordability issues.[38] A financing incidence analysis showed that the wealthiest people invest more money for his/her households' health concerns.[39] Several past studies demonstrated that households' wealth position is a motivating factor for handwashing practice.[23,24,41] Therefore, this issue should be taken into account when designing any behavior change intervention to ensure that resources are directed to those who are in need, such as people living in disadvantaged areas and of low socio-economic status. This study found that the location of handwashing significantly affected the overall inequality in the use of antimicrobial agents during handwashing. Therefore, interventions should prioritize the availability of various antimicrobial agents along with a specified place for handwashing, specifically targeting the disadvantageous segment of the population. Handwashing is also significant while providing health care services.[42] Handwashing with soap and water can help in preventing nosocomial infections, according to a

Table 4
Decomposition of concentration index for handwashing.

Variables	Contribution to overall CI = 0.597			
	Elasticity	CI	Absolute contribution	Percentage contribution
Age of the household head (years)				
<31	−0.005	−0.042	0.001	0.142
31–50	−0.001	0.045	0.000	−0.026
51–65	0.004	0.014	0.000	0.036
65+ (ref.)	–	–	–	–
Total			0.001	0.152
Sex of the household head				
Male (ref.)				
Female	0.001	−0.007	0.000	−0.005
Highest educational level of the household head				
No formal education (ref.)				
Primary education	0.008	−0.166	−0.005	−0.826
Secondary education	0.013	0.177	0.009	1.531
Higher education	0.011	0.300	0.013	2.087
Total			0.017	2.792
Highest educational level of women				
No formal education (ref.)				
Primary education	0.003	−0.167	−0.002	−0.347
Secondary education	0.013	0.159	0.008	1.371
Higher education	0.007	0.234	0.006	1.015
Total			0.012	2.039
Households size				
<3 members (ref.)				
3–4 members	0.005	0.007	0.000	0.024
5six members	0.000	−0.006	0.000	−0.001
7 or above members	0.001	0.032	0.000	0.018
Total			0.000	0.041
Type of place for handwashing				
Covered space (ref.)				
Unshared open space	−0.065	−0.138	0.036	5.969
Shared open space	−0.142	−0.343	0.195	32.288
Total			0.231	38.256
Mass media exposure (radio/television)				
Have access	0.015	0.726	0.045	7.404
No access (ref.)				
Sources of drinking water				
Improved (ref.)				
Unimproved	−0.001	−0.027	0.000	0.023
Hygienic toilet facilities				
Yes	0.032	0.573	0.074	12.249
No (ref.)				
Sharing of toilet				
Yes (ref.)				
No	0.055	0.161	0.036	5.901
Place of residence				
Urban	0.005	0.497	0.009	1.470
Rural (ref.)				
Division				
Dhaka	0.002	0.187	0.002	0.303
Chattogram	0.003	0.071	0.001	0.143
Rajshahi	0.010	−0.024	−0.001	−0.152
Rangpur	0.013	−0.121	−0.006	−1.023
Khulna	0.002	0.038	0.000	0.054
Sylhet (ref.)	–	–	–	–
Barisal	−0.004	−0.074	0.001	0.204
Mymensingh	0.000	−0.083	0.000	0.016
Total			−0.003	−0.455
Wealth index				
Poorest (ref.)	–	–	–	–
Poorer	0.008	−0.310	−0.009	−1.538
Middle	0.020	0.004	0.000	0.056
Richer	0.043	0.313	0.054	8.866
Richest	0.087	0.668	0.233	38.704
Total			0.278	46.087
Explained CI			0.699	115.956
Residual CI			−0.102	15.956

CI, concentration index.

hospital-based study conducted in the USA.[43,44] However, one-third of the world's health facilities had no hand hygiene resources at the point of health delivery, which puts public health at risk.[4] Therefore, affordable and sturdy handwashing stations should be installed at the community level so that everyone can benefit from handwashing with antimicrobial agents.

Hygienic toilet facilities and exposure to mass media contributed 12% and 7.4% of total inequality of handwashing practices with

antimicrobial agents, respectively. According to a Vietnamese study, people who used more hygienic restrooms washed their hands with antimicrobial soap more frequently.[37] People who use better restrooms frequently are more concerned with personal hygiene than others.[45] Various studies have documented a positive correlation between mass media exposure and handwashing with soap and other antimicrobial agents.[46–48] Even though public and non-governmental organizations played a significant role in Bangladesh to promote handwashing through print, Internet, and electronic media, more rural targeted initiatives should be implemented, particularly for remote areas.[38] Furthermore, individuals need to be made aware of the benefits of washing hands with various antimicrobial agents. Our results suggest that a combined, and multifaceted intervention would be more effective for improving handwashing behavior. However, it is of utmost importance that appropriate efforts be undertaken to make antimicrobial agents available and affordable for all people. In addition, to promote and encourage handwashing habits, health education initiatives should be undertaken at the school, hospital, and community levels. This would help in protecting people from various infectious diseases linked to poor and inadequate hand hygiene practices in Bangladesh.

This study has several limitations. The first limitation is that it was based on cross-sectional data, which failed to establish a causal relationship. Second, we used the household asset-based wealth index as a proxy for the absence of income or expenditure data to assess households' economic status. Third, due to the unavailability of data, various potential confounders (e.g., affordability, handwashing techniques) that might affect the handwashing with antimicrobial agents could not be included in the analysis. Despite these limitations, the present study's strength is the utilization of high-quality and nationally representative household survey data from both the urban and rural areas of Bangladesh. Since the Bangladesh demographic health survey has been conducted for some years, the procedures have been tested and standardized to ensure high-quality data. Therefore, the findings can be treated as representative of the entire country.

Conclusion

This study showed that only 38% of Bangladeshi households wash their hands with antimicrobial agents. Household's wealth index was responsible for about 46% of the overall inequality of handwashing with antimicrobial agents while the type of place for handwashing variable contributed 38% of total inequalities. Hygienic toilet facilities (12%) and exposure to mass media (7.4%) are other determinants of total inequalities of handwashing with antimicrobial agents. To promote handwashing behavior, the availability of antimicrobial agents and water at the sites for handwashing should be increased and, more importantly, practical teaching programs should be implemented. The educational level of parents, household wealth index, access to improved sanitation facilities, and mass media exposure were associated with handwashing behavior. Further studies and regular programs aimed at promoting best hand hygiene practices and ensuring the availability of the necessary infrastructure at the community level should be prioritized to avoid and reduce the burden of infectious diseases in Bangladesh.

Author statements

Ethical approval

This study did not require ethical approval as it used unidentifiable secondary DHS data set. The BDHS data set is publicly available; however, approval was given upon request by the Measure Demographic and Health Survey (DHS) program office to use this data set. As per DHS, written informed consent was obtained from all participants enrolled in their survey.

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Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors made substantial contributions to the conception and design of the study, interpreted, and discussed the results, and all gave approval to the final article to be submitted. ARS and IZ conducted the analysis. ARS, IZ, NA, AA, and ZH drafted the manuscript. ARS, IZ, NA, AA, and ZH contributed to data acquisition.

Data availability statement

The electronic data sets can be freely downloaded from the DHS's Web site through the following link: https://dhsprogram.com/data.

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Review Paper

Key factors influencing paediatric COVID-19 vaccine hesitancy: a brief overview and Decision-making Trial and Evaluation Laboratory analysis

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ABSTRACT

Objectives: The purpose of this study was to examine the current literature on paediatric COVID-19 vaccine hesitancy among parents and identify key influencing factors, thus enabling targeted policy development and implementation.

Study design: This was a systematic literature review and Decision-making Trial and Evaluation Laboratory (DEMATEL) analysis.

Methods: A review of the quantitative and qualitative literature focusing on factors influencing paediatric COVID-19 vaccine hesitancy was conducted. Searches were performed in PubMed, ScienceDirect, SpringerLink and Embase. Because of the immediacy of the topic, commentaries were included in addition to research and review articles. Influencing factors were categorised according to the Health Ecology Theory and screened using the DEMATEL method.

Results: A total of 44 articles were included in the study, and 44 factors influencing paediatric COVID-19 vaccine hesitancy were identified. Of these, 18 were categorised as key factors using the DEMATEL method, including a history of COVID-19 infection in parents and perceived safety of the paediatric COVID-19 vaccine.

Conclusions: Policymakers and public health personnel should pay more attention to the key factors influencing paediatric COVID-19 vaccine hesitancy. The outcome of this research will benefit and motivate decision-makers to consider strategies to overcome various challenges of COVID-19 vaccine hesitancy.

Introduction

The novel coronavirus pneumonia (COVID-19) pandemic has resulted in more than 600 million confirmed cases, including approximately 6.6 million deaths.[1] In addition to the threat to health, COVID-19 also impacts the daily life and mental health of the public and thus continues to receive much attention from researchers worldwide.[1,2] According to the World Health Organisation, vaccines and vaccination are the most effective measures to halt the pandemic, thus emphasising the importance of vaccination.[3,4] Since the start of the pandemic, many countries have invested a lot of resources into the research, development and practical application of COVID-19 vaccines.[5–7] The age range of those eligible to receive the COVID-19 vaccination has extended from 18 to 59 years to ≥3 years in China[8] and was gradually liberalised from >12 years to all ages in Canada, meaning that children can also now receive the COVID-19 vaccination.[9]

Vaccine hesitancy refers to the delay in acceptance or refusal of vaccines, despite the availability of the vaccine. Vaccine hesitancy is complex and context specific, varying across time, place and vaccine.[10] The Strategic Advisory Group of Experts working group on vaccine hesitancy also recognised that vaccine hesitancy occurs along a continuum between full acceptance, including high demand for vaccines, and outright refusal of some or all vaccines, although acceptance of the vaccines was the norm in the majority of populations globally.[10] In this study, paediatric vaccine hesitancy refers to parental hesitancy about the paediatric vaccine because, in most cases, parents are the decision-makers regarding whether or not a child should be vaccinated.[2,11]

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Previous investigations into the factors influencing paediatric vaccine hesitancy often used specific theories and models (e.g. the Health Belief Model and the Theory of Planned Behaviour).[12,13] However, many researchers have pointed out that the insufficient inclusion of factors influencing vaccine hesitancy is a limitation of their studies,[14–16] and studies based on specific theoretical models may lack comprehensiveness. At the same time, a systematic review of the factors influencing influenza vaccine hesitancy noted that the review only described the influencing factors and could not judge their importance.[17] This is because when a factor is reported more frequently, it does not mean that it is more important but may simply be because of it being selected more often by the researcher or showing significance more often.[17] Therefore, comprehensive identification of the key factors influencing paediatric COVID-19 vaccine hesitancy can help to reduce the hesitancy rate and ultimately improve vaccination coverage.

According to previous research, the common theoretical models used in the study of influences on vaccine hesitancy include the Knowledge-Attitude-Practice Theory,[18,19] the Health Belief Model,[20,21] the Protection Motivation Theory[22] and the Theory of Planned Behaviour,[23] but they lack comprehensiveness to a certain extent. For example, these models lack policy-level constructs, such as culture and economics, when measured. In comparison, the Health Ecology Theory is more comprehensive and is derived from ecology theory.[24] McLeroy[24] applied ecology theory to the field of health promotion research in 1988 and argued that health promotion should focus on both individual and social factors, and more branches have since developed, including the Health Ecology Theory. According to the Health Ecology Theory, the determinants of health behaviours include (1) personal innate traits and disease biology; (2) personal psychology and behaviour; (3) interpersonal network; (4) living and working conditions; and (5) national and local social, economic, political, health, environmental conditions, and related policy factors.[24] The Health Ecology Theory emphasises that health behaviours are the result of the interdependence and interaction of many factors.

This study aimed to identify factors influencing paediatric COVID-19 vaccine hesitancy through a literature evaluation under the framework of the Health Ecology Theory and subsequently determine the key influencing factors through Decision-making Trial and Evaluation Laboratory (DEMATEL).

Methods

Literature search and selection procedure

The literature screening flowchart is shown in Fig. 1. The keywords used for the literature search included paediatric vaccine; paediatric vaccine hesitancy/hesitation; vaccine intention/willing/behaviour; influencing factor; factor; kid; child/children/parent/kids. The retrieval databases were PubMed, ScienceDirect, SpringerLink and Embase, and Boolean operators “AND,” “OR” and “NOT” were used for the combination of retrieval terms during the process. The two study authors (Yonyi Wang was responsible for reading, screening and excluding, while Xinping Zhang checked and proofread) screened the retrieved articles and eliminated those not meeting the study needs. The purpose of the included literature was to measure or evaluate factors influencing paediatric COVID-19 vaccine hesitancy. Case reports, clinical guidelines, recommendations and articles in non-English languages were excluded. We also excluded studies that investigated children with diseases because each vaccine may have specific considerations for particular populations and health conditions.[25]

In terms of selecting influencing factors, those with significant outcomes and those frequently reported in the literature were included. This selection process was checked by the two authors based on the principle of ‘consistency of content’ and then discussed to determine the correct categorisation. Some factors could be categorised without doubt (e.g. psychological factors could be categorised as Dimension 2). For controversial factors, reference was made to the previous DEMATEL literature.

DEMATEL

DEMATEL was proposed by Gabus and Fontela at the Geneva Research Centre for the Science and Human Affairs Program from 1972 to 1976. DEMATEL uses graph theory and matrix theory to (1) analyse the complex problems of interlocking influencing factors, (2) identify the causal relationship between complex system factors and (3) extract key elements.

The following steps were used in the current study to determine the key influencing factors:

Step 1. Factors influencing paediatric COVID-19 vaccine hesitancy were determined. A group of effective factors $S = \{S_1, S_2, \ldots \ldots, S_n\}$, with significant impact on the system were identified.

Step 2. An initial direct influence matrix was established. An expert panel was set up, including four experts in preventive medicine, two in paediatrics, two in social medicine and one in health management. Experts formulated the direct influence matrix $X=(x_{ij})_{n\times n}$ by indicating the influence that the factor S_i has on S_j, using an integer scale (0–4) of no influence (0); very low influence (1); small influence (2); moderate influence (3); very strong influence (4).

Step 3. A normalised direct influence matrix was calculated. The normalised direct influence matrix M can be obtained by normalising the initial direct influence matrix X according to the following equation.

$$M = X \Big/ \max_{1\le i\le n} \sum_{j=1}^{n} x_{ij}$$

Step 4. Based on matrix X, the total influence matrix $T = [t_{ij}]_{n\times n}$ was calculated by summing the direct effects and all of the indirect effects by

$$T = (t_{ij})_{n\times n} = M(I - M)^{-1}$$

where, I–identity matrix;

Step 5. The Prominence and Relation values were calculated

$$R_{i=} \sum_{j-1}^{n} t_{ij}\ , i = 1, 2, \ldots, n$$

$$C_{j=} \sum_{i-1}^{n} t_{ij}\ , j = 1, 2, \ldots, n$$

Prominence (R_i+C_j) describes the strength of influence given and received by a given factor. The Relation (R_i-C_j) shows the net effect that a given factor brings into the system and is the basis for ranking factors. If R_i-C_i is positive, then S_i belongs to a group of causes (impact the system). If R_i-C_i is negative, then S_i is the effect of the net impact of other system elements and is classified in the group of effects.

Step 6. A cause and effect diagram was plotted. According to the values of array ($R_i + C_j$, R_i-C_j), the causality diagram was drawn, with the Prominence as abscissa and the Relation as ordinate, the values of ($R_i + C_j$, R_i-C_j) were indicated in the figure (Fig. 2), and the visualised figure was used to represent the importance of factors in the system. A line was drawn with the mean of R + C values as the cut-off point to divide the causality map into four quadrants. Due to

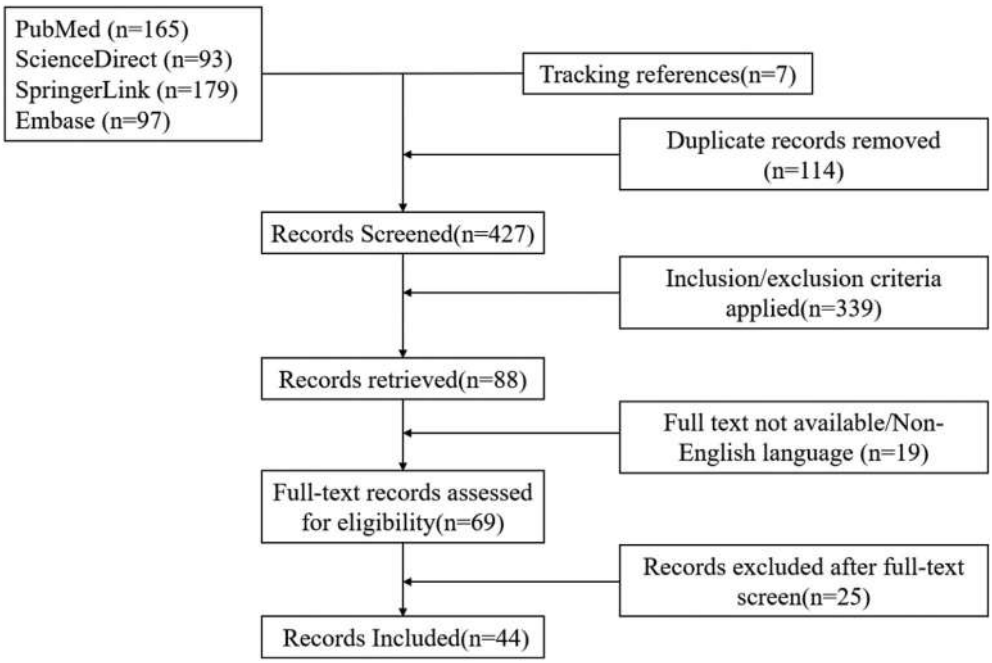

Fig. 1. Literature screening flowchart.

their location in a specific quadrant, factors are classified as most important, important, independent or indirect.[26]

Results

Systematic search results

Among the 44 articles identified during the search, 36 were cross-sectional studies, three were review articles, one was an intervention study, two were mixed methods studies (i.e. using both qualitative and quantitative research methods), one was a commentary and one was qualitative a study. The details of the selected studies are presented in Table 1. A total of 95,497 participants were involved in the studies included in this review.

From the included studies, most of the surveys were conducted using self-developed questionnaires. In these questionnaires, the outcome variable was parental paediatric COVID-19 vaccine hesitancy, and the questioning varied, mainly in terms of intention, willingness, propensity and attitude. Other main dimensions were sociodemographics (e.g. gender, age, region, economic status), vaccine safety, efficacy, priority, history of vaccination (e.g. influenza vaccination), perceived risk of COVID-19 and/or vaccine, negative COVID-19 experience, trust and psychological status. The current review identified 44 factors influencing paediatric COVID-19 vaccine hesitancy from the selected articles (Table 2).

DEMATEL analysis

Direct influence matrix, normalised direct influence matrix, total influence matrix and causality plots for dimension 1 are shown in Table 3 and Fig. 2 (data results for the remaining dimensions are shown in the Supplementary Material).

Key factors influencing paediatric COVID-19 vaccine hesitancy

Based on the method described earlier, the first quadrant, namely, the most important factors, were considered to be the key factors in this study. A total of 18 key factors were identified in this study. Of these, eight, five, five, two, and one factors were found in each of the five dimensions, respectively (see Table 4 for details).

Discussion

A total of 18 key factors influencing paediatric COVID-19 vaccine hesitancy were screened by the DEMATEL method.

Histories of illness of parents and children were found to be key influencing factors, regardless of whether their histories of illness were associated with COVID-19. First, paediatric COVID-19 vaccine hesitancy may be due to the fact that the vaccine itself has vaccination contraindications[67,68] (i.e. children who are in poor physical condition and have had allergic reactions after vaccination may be at risk of becoming more sensitive to drug reactions due to their vulnerability even if they do not meet the contraindications).[68,69] Second, parents with a history of disease may not have sufficient confidence and self-efficacy to take their children to healthcare facilities for vaccination.[70] From a genetic point of view, the physical condition of parents may also impact their children;[71,72] thus, parents may hold a wait-and-see attitude towards the COVID-19 vaccine in children because of concerns about the physical condition of their children. Parents who have previously been allergic to the vaccine may have concerns and fears about their children experiencing the same uncomfortable reactions, such as fever, nausea and dizziness.[64] In terms of the impact of parental history of COVID-19 infection on paediatric COVID-19 vaccine hesitancy, one explanation could be that people often experience unrealistic optimism in the face of familiar risks. Therefore, parents believe that the situation is largely under the control and will of the individual[73] and that they can protect their children well and do not need vaccines. If the child has been diagnosed with COVID-19, then their parents will think that infection with the virus will make the body produce antibodies and play a protective role, thereby reducing the perception of the necessity of the COVID-19 vaccine in children.[30]

The safety of COVID-19 vaccines has attracted much attention since their development and use. Due to the rapid spread of

Table 1
Literature information.

Author(s)	Study type	Region	Tool	Study period	Sample size
Humble RM et al.[9]	Cross-sectional study	Canada	Self-developed questionnaire	2020.12.20–2020.12.24	1702
Babicki M et al.[27]	Cross-sectional study	Poland	Self-developed questionnaire	2021.5.9–2021.5.14	4432
Zona S et al.[28]	Cross-sectional study	Italy	Self-developed questionnaire	2021.7.15–2021.8.16	1799
Kezhong A et al.[29]	Cross-sectional study	China	A 10-question adult vaccine hesitancy scale (aVHS)	2020.6–2020.7	13,451
Musa S et al.[30]	Cross-sectional study	Qatar	Vaccination scheduled records and information	2021.5.17–2021.6.3	4023
Skjefte M et al.[31]	Cross-sectional study	16 countries	Self-developed questionnaire	2020.10.28–2020.11.18	17,871
Fisher CB et al.[32]	Cross-sectional study	USA	Items from previous scales	2021.10	400
Xu Y et al.[8]	Cross-sectional study	China	Parental Attitudes About Childhood Vaccines (PACV)	2021.7.22–2021.8.14	917
Lackner CL et al.[33]	Cross-sectional study	Canada	Self-developed questionnaire	2020.5.15–2020.6.9	455
Wang Y and Zhang X[2]	Cross-sectional study	China	Parental Attitudes About Childhood Vaccines, PACV	2021.6–2021.7	382
Olusanya OA et al.[34]	Review	–	–	–	–
Kreuter MW et al.[35]	Cross-sectional study	USA	Self-developed questionnaire	2021.1.13–2021.1.31	1951
Russo L et al.[36]	Cross-sectional study	Italy	Self-developed questionnaire	2021.7.22–2021.8.31	1696
Cole JW[37]	Intervention study	USA	MOTIVE (MOtivational Interviewing Tool to Improve Vaccine AcceptancE)	2018.7–2019.6/ 2019.7–2020.3	2504/1954
Ellithorpe ME et al.[38]	Cross-sectional study	USA	Self-developed questionnaire	2020.11.13–2020.12.8	682
Phan TT[39]	Cross-sectional study	Mid-Atlantic	Self-developed questionnaire	2021.3.19–2021.4.16	513
Temsah MH et al.[40]	Cross-sectional study	Saudi Arabia	Vaccine Hesitancy Scale, VHS-Adjusted	–	3167
Alfieri NL et al.[41]	Cross-sectional study	USA	Self-developed questionnaire	2020.6.8–2020.6.29	1425
Teasdale CA et al.[42]	Cross-sectional study	USA	Self-developed questionnaire	2021.3.9–2021.4.11	1119
Xu Y et al.[43]	Cross-sectional study	China	Patient Health Questionnaire (PHQ-4) and self-developed questionnaire	2020.12.18–2020.12.31	4748
Bell S et al.[44]	Mixed Method Study	UK	Self-developed questionnaire	2020.4.19–2020.5.11	1252/19
Brandstetter S et al.[45]	Cross-sectional study	Germany	Self-developed questionnaire	2020.5.5–2020.5.28	612
Yılmaz M et al.[46]	Cross-sectional study	Turkey	Self-developed questionnaire	2021.2.8–2021.2.21	1035
Szilagyi PG et al.[47]	Cross-sectional study	USA	Vaccine Hesitancy Scale, VHS-Adjusted	2021.2.17–2021.3.30	1745
Gabriella DG et al.[48]	Cross-sectional study	Italy	Self-developed questionnaire	2021.4.18–2021.5.18	607
Ruggiero KM et al.[49]	Cross-sectional study	USA	Parental Attitudes About Childhood Vaccines, PACV	2020.11–2021.1	427
Teasdale CA et al.[50]	Cross-sectional study	USA	Self-developed questionnaire	2021.3.9–2021.4.2	2074
Urrunaga-Pastor D et al.[51]	Cross-sectional study	Latin America and Caribbean	Self-developed questionnaire	2021.5.20–2021.7.14	227,740
Kelly BJ et al.[52]	Cross-sectional study	USA	Self-developed questionnaire	2020.4	2247
Botha E et al.[53]	Review	–	–	–	–
Evans S et al.[54]	Mixed Method Study	Australia	Self-developed questionnaire	2020.4.8–2020.4.28/ 2021.1.18–2021.2.8	1094
Altulaihi BA et al.[55]	Cross-sectional study	Saudi Arabia	Self-developed questionnaire	–	333
Hetherington E et al.[56]	Cross-sectional study	Canada	Self-developed questionnaire	2020.5–2020.6	1321
Chemakina et al.[57]	Qualitative study	Russia	–	–	253
MacDonald NE and Dubé E[58]	Commentary	–	–	–	–
Wang Q et al.[14]	Cross-sectional study	China	Vaccine Hesitancy Scale, VHS	2020.9.21–2020.10.17	3095
Zhou Y et al.[59]	Cross-sectional study	China	Self-developed questionnaire	2020.7.1–2020.9.8	1071
Montalti M et al.[60]	Cross-sectional study	Italy	Self-developed questionnaire	2020.12–2021.1	5054
Aldakhil H et al.[61]	Cross-sectional study	Saudi Arabia	Vaccine Hesitancy Scale, VHS	2021.1.1–2021.2.28	270
Galanis P et al.[62]	Review	–	–	–	–
Middleman AB et al.[63]	Cross-sectional study	USA	Self-developed questionnaire	2020.8.11–2020.9.18/ 2021.2.4–2021.3.1/ 2021.6.10–2021.6.30	1613
Chiang, V. et al.[64]	Cross-sectional study	China	Medical records	2021.2–2021.6	1127
Goldman, R. D. et al.[65]	Cross-sectional study	USA	Self-developed questionnaire	2020.3.26–2020.5.31	1552
Wu Yue. et al.[66]	Cross-sectional study	China	Self-developed questionnaire	2021.6–2021.7	2538

COVID-19,[1] many countries invested in various resources to participate in vaccine development. Due to the urgency of the vaccine, there is a lack of long-term clinical trials and clinical evidence;[5,74] therefore, there are many doubts about the side-effects and potential future effects of COVID-19 vaccines.[27,40,44] Risk perception, including paediatric COVID-19 susceptibility, paediatric COVID-19 severity and paediatric COVID-19 transmission, can also influence vaccination decisions.[32] Since the start of the pandemic, official organisations in various countries, such as the World Health Organisation or the United States Food and Drug Administration, have issued a variety of information on vaccine research, development and vaccination. The level of public trust in official organisations/agencies, as well as in the online media messages they release, may seriously influence the vaccine decision-making process.[38,65] Willingness to vaccinate is stronger when the public trusts official organisations/institutions and when they provide a wealth of information on the development, testing and safety of the COVID-19 vaccine.[35] In addition, psychological distress,[43] that is, psychological status, has increasingly been shown to affect vaccination decisions, including but not limited to anxiety-depression.[51] In addition, some other psychological factors, such as psychological flexibility[2] and

Table 2
Factors influencing paediatric COVID-19 vaccine hesitancy from the selected articles.

No.	Factors	Details
a. Dimension 1. Personal innate traits and disease biology.		
S1	Gender[27,38,42,52,60,62]	
S2	Age[28,33,35,40,47,51,55,60,62]	
S3	Age of child/children[30,36,40,48,55,60]	
S4	History of COVID-19 infection in parents[30,51,65]	
S5	History of parental vaccine allergy[64]	
S6	History of parental immunodeficiency/immune disease[57]	
S7	History of parental critical/chronic illness[31]	
S8	History of COVID-19 infection in child/children[8,65]	
S9	History of child/children vaccine allergy[61,65]	
S10	History of childhood immunodeficiency/immune disease[49,61,65]	
S11	History of childhood critical/chronic illness[28,65]	
b. Dimension 2. Personal psychology and behaviour.		
S12	Perceived the safety for paediatric COVID-19 vaccine[8,14,27,28,31,32,36,42,44,47,49,50,53,55,56,61,63]	Side-effects of paediatric COVID-19 vaccine; rapid development leading to insufficient safety information and evidence; unclear potential future impact
S13	Perceived the need for paediatric COVID-19 vaccine[9,40,50]	Vaccinating children against COVID-19 is necessary or not
S14	Perceived the efficacy for paediatric COVID-19 vaccine[8,27,28,31,32,36,38,40,42,44,48,50,56]	Duration of protection for paediatric COVID-19 vaccine; vaccination can completely protect children from infection or not
S15	Perceived the importance for paediatric COVID-19 vaccine[31]	Importance and priority of paediatric COVID-19 vaccination
S16	Risk perception of COVID-19[31,32,36,48,53,54,62]	Paediatric COVID-19 susceptibility; paediatric COVID-19 severity; paediatric COVID-19 transmission risk
S17	Influenza vaccination[9,48,55,59,62]	History of influenza vaccination; willingness to receive influenza vaccination
S18	Paediatric influenza vaccination[38,39,49,62]	History of paediatric influenza vaccination; willingness to receive paediatric influenza vaccination
S19	COVID-19 vaccination[9,29,32,39,40,42,46–48,62]	History of COVID-19 vaccination; willingness to receive COVID-19 vaccination
S20	Paediatric routine vaccination[8,31,33,56,62]	Pay attention to vaccination within the childhood immunisation programme; routine vaccination for children is timely and complete
S21	Trust in health authorities/personnel and information issued[28,31,34,54,62]	Confidence in health authorities (e.g. hospitals)/personnel and information issued
S22	Trust in official agency/organisation and information issued[31,45,62]	Confidence in official agency/organisation (e.g. health committees) and information issued
S23	Compliance with infection prevention and control measures[31,51]	Compliance with mask-wearing, maintaining social distance, etc.
S24	Psychological avoidance[33]	Tend to avoid thoughts, negative emotions, or information about the outbreak
S25	Psychological distress[43,51]	E.g. mood disorder, depression, anxiety
S26	Coping style[2]	The methods and strategies adopted by individuals with personal characteristics in order to reduce or avoid stress and adapt to environment
S27	Self-efficacy[2,53]	A person's subjective judgement of whether he or she is able to successfully perform a behaviour
S28	Psychological flexibility[2]	Individual consciously adapts to the present and adheres to or changes behaviour guided by personal values
S29	Protection[14,44]	Protect people around; protect children
c. Dimension 3. Interpersonal network.		
S30	Occupation[8,9,28,46,59]	Occupation category; non-medical-related occupation and medical-related occupation
S31	Revenue[8,28,32,35,44,50,56,62]	Annual household income (RMB)
S32	Education level[14,28,32,40,47,50,51,53,56,59–61]	Education; education Level
S33	Community support[32]	Vaccine-related support from other parents or family members
S34	Cognition/attitude/suggestion/communication of healthcare providers[28,34,37,47,48,54,58]	Healthcare providers' perception and attitude towards paediatric COVID-19 vaccine; healthcare providers can provide effective advice; effectively communicate with healthcare providers
d. Dimension 4. Living and working conditions.		
S35	Accessible information sources[27,40,41,54,63]	Multiple sources of information such as media information, network information and official information are accessible
S36	Source of information relied on[60]	One or more sources of information that relied on
S37	Information content breadth[40,55]	The information content is extensive and covers content that has attracted much parental attention such as adverse events and vaccine information
S38	Experienced COVID-19[38]	Experienced the COVID-19 outbreak
S39	Participate in COVID-19 prevention and control[66]	Have participated in the work related to the prevention and control of COVID-19 epidemic
S40	History of exposure to vaccine adverse events in children[29]	Heard of adverse events to paediatric vaccines
e. Dimension 5. National and local social, economic, political, health, environmental conditions and related policy factors.		
S41	Permanent residence[8,30,51]	Resident area
S42	Household registration[8,30]	Consistent with or inconsistent with permanent residence; rural household registration or urban household registration
S43	Compulsory policy/measure[60]	E.g. School policy for compulsory COVID-19 vaccination of children
S44	Incentive policy/measure[34]	E.g. obtaining material rewards after vaccination

Table 3
Direct-influence matrix, normalized direct-influence matrix and total-influence matrix of Dimension 1.

	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10	S11
a. Dimension 1. Direct influence matrix.											
S1	0	1.0000	1.6667	2.2222	2.2222	2.3333	1.7778	1.8889	2.0000	2.2222	1.8889
S2	1.0000	0	1.8889	2.1111	1.8889	2.1111	2.0000	2.1111	2.0000	2.2222	2.2222
S3	1.5556	1.6667	0	2.5556	2.4444	2.4444	2.3333	2.5556	2.4444	2.5556	2.3333
S4	1.3333	1.6667	2.0000	0	2.1111	2.3333	2.0000	2.5556	2.7778	2.4444	2.1111
S5	1.1111	1.3333	1.7778	2.6667	0	2.4444	2.2222	2.5556	2.8889	2.5556	2.3333
S6	1.1111	1.5556	1.8889	2.5556	2.6667	0	2.4444	2.7778	2.6667	2.5556	2.4444
S7	1.4444	2.0000	1.7778	2.3333	2.2222	2.4444	0	2.3333	2.6667	2.3333	2.3333
S8	1.3333	1.7778	1.8889	2.4444	2.5556	2.2222	2.0000	0	2.4444	2.5556	2.3333
S9	1.3333	1.7778	2.5556	2.5556	2.7778	2.6667	2.3333	2.6667	0	2.4444	2.3333
S10	1.2222	1.5556	2.1111	2.4444	2.6667	2.8889	2.3333	2.4444	2.5556	0	2.3333
S11	1.2222	1.7778	2.4444	2.3333	2.4444	2.6667	2.4444	2.2222	2.3333	2.3333	0
b. Dimension 1. Normalised direct influence matrix.											
S1	0	0.0427	0.0711	0.0948	0.0948	0.0995	0.0758	0.0806	0.0853	0.0948	0.0806
S2	0.0427	0	0.0806	0.0900	0.0806	0.0900	0.0853	0.0900	0.0853	0.0948	0.0948
S3	0.0664	0.0711	0	0.1090	0.1043	0.1043	0.0995	0.1090	0.1043	0.1090	0.0995
S4	0.0569	0.0711	0.0853	0	0.0900	0.0995	0.0853	0.1090	0.1185	0.1043	0.0900
S5	0.0474	0.0569	0.0758	0.1137	0	0.1043	0.0948	0.1090	0.1232	0.1090	0.0995
S6	0.0474	0.0664	0.0806	0.1090	0.1137	0	0.1043	0.1185	0.1137	0.1090	0.1043
S7	0.0616	0.0853	0.0758	0.0995	0.0948	0.1043	0	0.0995	0.1137	0.0995	0.0995
S8	0.0569	0.0758	0.0806	0.1043	0.1090	0.0948	0.0853	0	0.1043	0.1090	0.0995
S9	0.0569	0.0758	0.1090	0.1090	0.1185	0.1137	0.0995	0.1137	0	0.1043	0.0995
S10	0.0521	0.0664	0.0900	0.1043	0.1137	0.1232	0.0995	0.1043	0.1090	0	0.0995
S11	0.0521	0.0758	0.1043	0.0995	0.1043	0.1137	0.1043	0.0948	0.0995	0.0995	0
c. Dimension 1. Total influence matrix.											
S1	0.6503	0.8667	1.0709	1.2811	1.2751	1.2987	1.1620	1.2715	1.3065	1.2792	1.1989
S2	0.7023	0.8400	1.0963	1.2968	1.2825	1.3106	1.1886	1.2994	1.3266	1.2990	1.2301
S3	0.8264	1.0370	1.1810	1.5024	1.4912	1.5144	1.3736	1.5054	1.5377	1.5003	1.4124
S4	0.7715	0.9780	1.1880	1.3185	1.3946	1.4239	1.2836	1.4198	1.4612	1.4109	1.3240
S5	0.7820	0.9898	1.2091	1.4552	1.3462	1.4628	1.3230	1.4544	1.5010	1.4492	1.3643
S6	0.8047	1.0268	1.2479	1.4930	1.4897	1.4104	1.3690	1.5039	1.5361	1.4908	1.4075
S7	0.7907	1.0096	1.2036	1.4369	1.4261	1.4562	1.2306	1.4398	1.4861	1.4349	1.3584
S8	0.7771	0.9892	1.1929	1.4236	1.4206	1.4309	1.2934	1.3320	1.4608	1.4255	1.3419
S9	0.8356	1.0633	1.3063	1.5347	1.5349	1.5545	1.4032	1.5418	1.4766	1.5287	1.4429
S10	0.8055	1.0224	1.2507	1.4833	1.4840	1.5144	1.3599	1.4865	1.5262	1.3867	1.3981
S11	0.7947	1.0168	1.2456	1.4592	1.4559	1.4863	1.3455	1.4583	1.4975	1.4571	1.2887

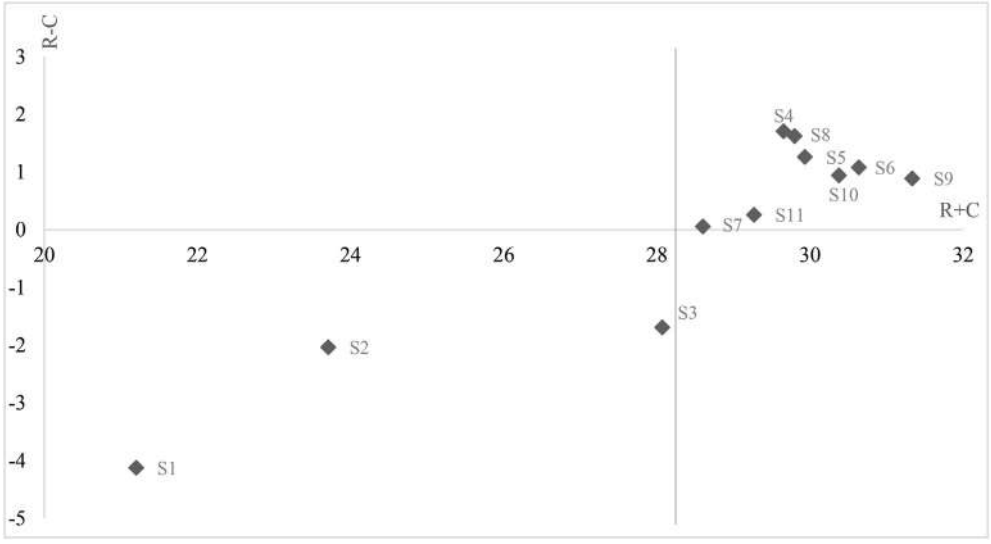

Fig. 2. Dimension 1. Cause and effect diagram.

trauma,[70] have also been reported to impact vaccine decision-making.

In general, the educational level of parents affects their perception of the paediatric COVID-19 vaccine; however, the impact of this effect is uncertain. Educational attainment is associated with greater participation in protective and preventive behaviours, which may be because higher education may help people engage in safe behaviour, while protecting them from the irrational fear of being infected or dying.[75] On the other hand, highly educated individuals usually possess high levels of self-

Table 4
Key factors influencing paediatric COVID-19 vaccine hesitancy.

No.	Factors	R+C	R − C
Personal innate traits and disease biology			
S4	History of COVID-19 infection in parents	29.6589	1.7106
S5	History of parental vaccine allergy	29.9378	1.2638
S6	History of parental immunodeficiency/immune disease	30.6427	1.0835
S7	History of parental critical/chronic illness	28.6055	0.0595
S8	History of COVID-19 infection in child/children	29.8009	1.6248
S9	History of child/children vaccine allergy	31.3389	0.8937
S10	History of childhood immunodeficiency/immune disease	30.3802	0.9449
S11	History of childhood critical/chronic illness	29.2729	0.2617
Personal psychology and behaviour			
S12	Perceived the safety for paediatric COVID-19 vaccine	29.1420	0.1584
S16	Risk perception of COVID-19	29.7677	0.5556
S22	Trust in official agency/organisation and information issued	29.0222	0.3786
S25	Psychological distress	27.8212	0.0557
S29	Protection	28.7056	0.5612
Interpersonal network			
S32	Education level	16.1452	0.5318
S34	Cognition/attitude/suggestion/communication of healthcare providers	16.4356	0.2530
Living and working conditions			
S38	Experienced COVID-19	33.4702	0.9357
S39	Participate in COVID-19 prevention and control	34.7912	0.9212
National and local social, economic, political, health, environmental conditions and related policy factors			
S44	Incentive policy/measure	10.0354	0.1046

efficacy[76] and are more confident in their ability to protect themselves and their children (i.e. believing in oneself outweighs believing in a vaccine where the risks remain). Unlike official organisations/institutions, healthcare providers are the most accessible professional help to parents. Healthcare providers' perceptions and attitudes towards paediatric COVID-19 vaccine and communication between parents and healthcare providers about the paediatric COVID-19 vaccine have all been shown to be important.[34,58] In addition, in terms of local practical policies, we found that some incentive schemes can encourage parents, to some extent, to vaccinate their children. It is easy to see from motivation-related theory that a certain degree of reward is an effective way to promote behaviour.[77]

Previous research has divided the Health Ecology Theory framework into upstream, midstream and downstream sections and formed a chain of health behavioural influences, with upstream influencing midstream and midstream influencing downstream.[78] Dimensions 3, 4 and 5 are upstream factors influencing health behaviour, dimension 2 is a midstream factor and dimension 1 is a downstream factor.[78] From a public health perspective, policy makers and public health personnel play an important role in upstream influencing. For example, they can work together to develop incentives or benefits to encourage health behaviours, train healthcare providers in health awareness and communication skills, and the government or official institutions can introduce policies to improve the level of education of individuals and increase the transparency of health information. As a result, the substantive and positive role played by policy makers and health professionals can spread from top to bottom.

This study has some limitations. First, the DEMATEL analysis relies on expert scores, which are highly subjective. Each expert has limited experience in dealing with paediatric COVID-19 vaccine hesitancy; further research and a larger study sample size would make the results more robust. Second, paediatric vaccine hesitancy involves multiple disciplines, such as preventive health, public health and health management, and experts from different specialities may have different views on the factors influencing paediatric COVID-19 vaccine hesitancy, which can lead to deviations between the results calculated by DEMATEL and the actual situation. Finally, the literature is constantly being updated, and additional factors influencing paediatric COVID-19 vaccine hesitancy may be discovered in the future.

Conclusions

Overcoming COVID-19 vaccine hesitancy and realising herd immunisation are worldwide common goals at present. This study used a comprehensive theory to screen for key factors influencing paediatric COVID-19 hesitancy. The study findings are in line with the Determinants of Vaccine Hesitancy Matrix reported by the Strategic Advisory Group of Experts working group on vaccine hesitancy. The key factors influencing paediatric COVID-19 hesitancy that have been identified in this study emphasise the importance of policy development, and prevention and control practice.

Author statements

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Ethical approval

The studies involving human participants were reviewed and approved by the ethics committee of Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei,

China. As the study used anonymous, pooled and retrospective data, the ethics committee waived the need for participants to provide written informed consent. The study complies with the Declaration of Helsinki. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

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Competing interests

None declared.

Author contributions

Y.W. contributed to conceptualisation; data curation; investigation; formal analysis; methodology; visualisation; and writing, reviewing and editing the article. X.Z. contributed to conceptualisation; project administration; supervision; validation; and reviewing and editing the article.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.11.015.

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Original Research

Levels of physical activity and sitting time in women with infants, toddlers and preschoolers: a population-based cross-sectional study

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ABSTRACT

Objectives: Insufficient physical activity (PA) and prolonged sitting time (ST) increase the risk of chronic disease and mortality. Caring for young children can potentially impact maternal PA and sedentary behaviours. The aims of this study were to explore the levels of PA and ST in women with young children (infants, toddlers and preschoolers) and sociodemographic and behavioural factors associated with these.
Study design: This was a population-based cross-sectional study.
Methods: Survey 5 data collected in 2009 (n = 4290) of the 1973–1978 birth cohort of the Australian Longitudinal Study on Women's Health were used. Multiple linear and logistic regression models were used to examine associations.
Results: In adjusted models, compared with women with preschoolers, women whose youngest child was an infant aged 0–6 months, aged >6–12 months or toddler had lower PA (−321.3 MET.min/week [95% confidence interval (CI) −416.2, −226.4], −147.9 MET.min/week [95% CI −237.6, −58.1] and −106.4 MET.min/week [95% CI −172.3, −40.5]). ST was higher in women whose youngest child was an infant aged 0–6 months (0.48 h/day; 95% CI 0.19, 0.77) but lower with infants aged >6–12 months (−0.33 h/day; 95% CI −0.60, −0.05) and toddlers (−0.40 h/day; 95% CI −0.60, −0.20) than in those with preschoolers. The findings were similar in the logistic model. Sociodemographic and behavioural factors such as occupation and marital status also influenced PA and ST.
Conclusions: Women with infants and toddlers have lower PA than women with preschoolers. Women are more likely to sit more in the first 6 months after childbirth. These findings can inform resources and intervention development to improve activity levels in women with young children through consideration of the age of the youngest child, sociodemographic and behavioural factors.

Introduction

The health benefits of physical activity (PA) have been clearly established in literature.[1] PA is important for the prevention of chronic diseases such as obesity, cardiovascular disease, diabetes, osteoporosis and some cancers.[1] PA after childbirth is beneficial for the reduction of symptoms of postpartum depression, improving mood and general well-being and supporting weight loss and maintenance.[2–5] ST is a common measure of sedentary behaviour, which is defined as any waking behaviour characterised by energy expenditure ≤1.5 metabolic equivalents while in a sitting, reclining or lying posture.[6,7] Prolonged sitting time (ST) of 8 h or more has been associated with increased risk of chronic diseases and higher all-cause mortality independent of PA.[8,9]

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Despite its benefits, PA declines in some women during pregnancy due to concerns about foetal well-being, changing body shape and fatigue.[3,10] In the early postpartum period, pain and discomfort (depending on the mode of delivery) and sleep deprivation (due to infant care) may impact activity levels.[11,12] Evidence suggests that the decline in PA extends into the years after childbirth because of the considerable care needs of young children and an inherent increase in family obligations.[10,13–15] ST on the other hand is reported to decrease after having children,[16] consistent with reports of increased household activities for mothers with young children.[14] Although household activities contribute to overall PA, research suggests that few are at sufficient intensity to provide the benefits of moderate–vigorous activities, which are associated with meeting PA guidelines.[17]

Previous studies have focused primarily on the first 12 months after birth,[18–20] the impact of having children or the number of children on PA and ST.[21–24] There is a paucity of data on PA and ST in mothers beyond the first postpartum year and how these might differ with the child's age.[14] Although there have been reports of lower PA levels in mothers with children <6 years old, it is yet to be explored whether activity levels differ within this early childhood window, that is, infants, toddlers or preschoolers.[25] There is some evidence to suggest that the early years of child development (i.e. from birth to school age) is a time when women incur greater responsibility for childcare than men.[14,25] Care responsibilities, interrupted sleep patterns and employment all potentially influence the mother's activity levels.[23,25] Improved understanding of PA levels and ST at this life stage, and factors associated with these, could inform the development of tailored interventions for mothers with young children. The aims of this study were therefore to explore PA levels and ST in women with young children (infants, toddlers and preschoolers) and the sociodemographic and behavioural factors associated with these.

Methods

Study population

The Australian Longitudinal Study on Women's Health (ALSWH) is a national population-based prospective cohort study exploring factors that influence health and well-being of Australian women. At inception in 1996, three cohorts of women born 1921–1926, 1946–1951 and 1973–1978 were randomly selected from the national health insurance database, which includes all Australian citizens and permanent residents.[26] In 2013, a fourth cohort born 1989–1995 was recruited. The details of recruitment processes and cohort profile have been published.[27,28] Cross-sectional data for the present study were taken from survey 5 (2009) of the 1973–1978 cohort who completed mailed surveys every 3 years. The survey interval precludes the use of longitudinal data for this analysis, as some women had multiple births between surveys, and it was not possible to delineate prepregnancy data from postpartum data across surveys. Only parous women with the youngest child aged <6 years (n = 4290) were included in this study. The study was approved by the Ethics Committees of the University of Newcastle (h-076-0795) and the University of Queensland (200400224) Australia. All participants gave written informed consent.

Outcome variables

PA was measured using a modified version of the Active Australia Physical Activity Survey.[29,30] Participants were asked to report the frequency and duration of a variety of activities performed in the previous week for at least 10 min. These included walking for transport or recreation and moderate- and vigorous-intensity leisure-time activity. PA was calculated as sum of the products of total weekly minutes in each of the three categories of PA and the metabolic equivalent value (MET.min/week) assigned to each category: (3.33 MET × walking minutes) + (3.33 MET × moderate-intensity activity minutes) + (6.66 MET × vigorous-intensity activity minutes). Values were truncated at 5600 MET.min/week (equivalent to 1680 min/week) to avoid errors relating to over reporting.[31] PA was categorised as not meeting recommendations (<500 MET.min/week) or meeting recommendations (≥500 MET.min/week, equivalent to 150 min/week of moderate-intensity PA or 75 min/week of vigorous-intensity PA).

Participants were asked to report the time (hours and minutes) they typically spent sitting down while doing things such as visiting friends, driving, reading, watching television or working at a desk or computer on a usual weekday and separately on a usual weekend day. An estimate of average daily ST was calculated as (weekday sitting × 5 + weekend sitting × 2)/7. ST was categorised as high (≥8 h/day) or low (<8 h/day).[9]

Exposure variable

The exposure variable, age of the youngest child, was computed as the difference between the date of return of survey 5 and the date of birth of the youngest child. This was categorised as follows: infants aged 0–6 (birth to 182 days), infants aged >6–12 (183–365 days), toddlers aged >12–36 (366–1095 days) or preschoolers aged >36–72 (1096–2190 days) months. This categorisation was informed by the compulsory age of schooling in Australia (6 years) and the Australian Government's classification of infants, toddlers and preschoolers.[32] The infant category was split into 0–6 and >6–12 to take into account changing feeding and sleeping patterns in infancy.[33,34]

Covariates

The following self-reported measures were included as covariates: age (years); body mass index (BMI; calculated from height and weight); marital status (married/de facto or not married/partnered); number of children (1, 2 or ≥3); currently breastfeeding (yes or no); currently pregnant (yes or no); caesarean birth (yes or no); annual household income (low [0–36,399], medium [36,400–77,999] or high income [>77,999] Australian dollars per annum); occupation (no paid, clerical, associate professional or professional job); education (no formal/high school, trade/diploma, degree or higher); smoking status (yes or no); childcare use (yes or no); alcohol intake (categorised using National Health and Medical Research Council guidelines as non-drinker, rare drinker [less than monthly], low-risk drinker [up to 14 drinks/week] or risky/high-risk drinker [≥15 drinks/week]); self-rated health (fair/poor, good, very good or excellent); having difficulty sleeping in the last 12 months (yes or no). Accessibility/Remoteness Index of Australia (ARIA+; major cities, inner regional, outer regional or remote/very remote Australia) was used to assess the geographic location. Depression was assessed using the 10-item *Centre for Epidemiological Studies Depression Scale* with a score of ≥10 used as a categorical cutoff for clinically significant symptoms.[35] Anxiety was assessed using the anxiety subscale of the *Goldberg Depression and Anxiety Scale* with a score of ≥5 used as a categorical cutoff for risk of clinical anxiety. Stress was assessed by the *Perceived Stress Questionnaire*, which has been previously validated in the ALSWH. Values were analysed as mean of the multi-item summed score for perceived stress ranging from 0 to 4, with higher values referring to more stress.[36,37]

Statistical analysis

Comparisons were made between groups of women according to the age of the youngest child using one-way analysis of variance or Kruskal–Wallis test for continuous variables and Chi-squared tests for categorical variables. Multiple linear regression analyses were performed to examine the associations of age of youngest child with PA and ST and logistic regression analyses to examine associations with meeting PA recommendations and reporting low ST. Covariates were included based on known clinical relevance or association with outcome and exposure variables in bivariate analysis at $P \leq 0.2$. The fully adjusted model for the outcome PA included age, BMI, marital status, current pregnancy status, smoking status, alcohol intake, education, household income, depression, anxiety, stress, difficulty sleeping in the past 12 months, self-rated health, ARIA+ and childcare use. The fully adjusted model for the outcome ST included age, BMI, marital status, breastfeeding status, number of children, alcohol intake, household income, occupation, depression, anxiety, stress, difficulty sleeping in the past 12 months, self-rated health, ARIA+ and childcare use. The associations of sociodemographic and behavioural factors with PA and ST were also explored using estimates from the adjusted regression models. In sensitivity analysis, we tested interaction effects of caesarean birth and breastfeeding with age of the youngest child to explore differences in effects on PA and ST. All *P* values were calculated from two-tailed tests of statistical significance with a type 1 error rate of 5%. Stata software version 16 (Stata Corp, College Station, Texas, USA) was used for analysis.

Results

Participant characteristics

Table 1 shows the characteristics of the participants. Of 4290 women included in this study, 43% met PA recommendations, and 86% reported low ST. The proportion of women meeting PA recommendations was 35% of women with infants aged 0–6 months, 44% of women with infants aged >6–12 months, 43% of women with toddlers and 46% of women with preschoolers. Notably, the proportion of women meeting PA recommendations was lowest in the first 6 months after birth. The proportion of women reporting low ST was 78% of women with infants aged 0–6 months, 88% among women with infants aged >6–12 months and toddlers and 86% of women with preschoolers. Notably, ST was highest in the first 6 months after birth. Women with preschoolers as their youngest child had higher BMI, were more likely to be unmarried/unpartnered, have ≥3 children and to be current smokers and risky/high-risk drinkers. They were less likely to have a degree, high household income, a professional job, be currently employed and live in a major city.

Associations of PA and ST with the age of the youngest child

PA levels were lower in women whose youngest child was an infant aged 0–6 months (−321.3 MET.min/week; 95% CI −416.2, −226.4), infant aged >6–12 months (−147.9 MET.min/week; 95%CI −237.6, −58.1) or toddler (−106.4 MET.min/week; 95% CI −172.3, −40.5) than in women with preschoolers (Table 2). Women whose youngest child was an infant aged 0–6 or >6–12 months had lower odds of meeting PA recommendations than women with preschoolers as their youngest child (odds ratio [OR] 0.46; 95% CI 0.35, 0.59 and OR 0.77; 95% CI 0.61, 0.98, respectively; Supplementary Table S1). Women whose youngest child was an infant aged 0–6 months reported longer ST (0.48 h/day; 95% CI 0.19, 0.77) than women with preschoolers as their youngest child. Women whose youngest child was an infant aged >6–12 months or toddler reported shorter ST (−0.33 h/day; 95% CI −0.60, −0.05 and −0.40 h/day; 95%CI −0.60, −0.20 respectively) than women with preschoolers as their youngest child. Women whose youngest child was an infant aged 0–6 months had lower odds (OR 0.55; 95% CI 0.39, 0.76) of reporting low ST than those with preschoolers as their youngest child. The odds of reporting low ST was higher in women with toddlers (OR 1.3; 95% CI 1.03, 1.72) than in women with preschoolers as their youngest child (Supplementary Table S2).

Factors associated with levels of PA and ST

Being older, heavier or pregnant was associated with lower levels of PA, and being unmarried/unpartnered or having better self-rated health was associated with higher PA levels (Table 2). Being heavier, a non-drinker, having a high income, having a job or being more stressed was associated with longer ST. Having more than one child or living in outer regional Australia (living in a major city) was associated with shorter ST (Table 3). Among women whose youngest child was an infant aged 0–6 months, those who experienced caesarean birth were more likely to sit more than those who did not, in the first 6 months after childbirth (interaction effect on ST, OR 0.47; 95% CI 0.24, 0.94, data not shown).

Discussion

This cross-sectional study provides insight into the differences in PA and ST among women with infants, toddlers and preschoolers and the sociodemographic and behavioural factors associated with these behaviours. We report that PA levels were lower in women whose youngest child was aged 0–6 months, aged >6–12 months or a toddler than in women with preschoolers as their youngest child. We also found that women with infants aged 0–6 months reported higher ST, whereas women with infants aged >6–12 months or toddlers reported lower ST than those with preschoolers as their youngest child.

In the present study, only 43% of all women met the PA recommendation of ≥500 MET.min/week, which is in line with population estimates for Australian women.[38] This could be attributable to barriers faced by women with young children, such as fatigue, time limitations, lack of access to childcare, lack of social support and prioritising family obligations over self-care.[13,14] Previous research has demonstrated that having access to social support and childcare is paramount to alleviating PA barriers in mothers.[14] From our study, it was not possible to determine whether or when PA rebounds to prepregnancy levels. However, recent longitudinal analyses of data from the same ALSWH cohort suggest that PA levels are lower after 6 years in women who had children than in those who remained childless over the same period.[24] Lower levels of PA were reported in both primiparous and multiparous women, which may indicate that women do not rebound to previous levels of PA.[24]

In particular, women within the first 6 months after childbirth had the lowest PA level, which may reflect the time needed for parenting and infant care. A systematic review reported declines in levels of PA for both mothers and fathers after becoming parents, suggesting that the decline was associated with caring for the young child.[14] Given the benefits of PA for physical and mental health and well-being,[2,39] it is important to encourage resumption of PA as soon as it is safe to do so. Postpartum PA guidelines suggest that mild- to moderate-intensity PA such as pelvic floor exercises, strengthening, stretching and walking may commence immediately or as soon as is comfortable to do so in women who experienced uncomplicated pregnancy and delivery.[40] It is recommended

Table 1
Participant characteristics at survey 5 by the age of the youngest child ($N = 4290$).

Characteristic	Infants, 0–6 months	Infants, >6–12 months	Toddlers, >12–36 months	Preschoolers, > 36–72 months	Overall	*P*-value
	$n = 537$ (12.5%)	$n = 594$ (13.9%)	$n = 1883$ (43.9%)	$n = 1276$ (29.7%)	$N = 4290$ (100%)	
Meeting PA recommendations ≥500 MET.min/week *n* (%)						**0.001**
No	343 (65.0)	321 (55.7)	1034 (56.9)	673 (54.4)	2371 (57.0)	
Yes	185 (35.0)	255 (44.3)	782 (43.1)	564 (45.6)	1786 (43.0)	
Physical activity levels (MET.min/week), median ± IQR	299.7 ± 699.3	432.9 ± 832.5	399.6 ± 799.2	466.2 ± 882.5	399.6 ± 815.9	**<0.001**
Sitting time						**<0.001**
Low <8 h/day	402 (78.1)	507 (88.0)	1551 (88.4)	1023 (86.3)	3483 (86.4)	
High ≥8 h/day	113 (21.9)	69 (12.0)	204 (11.6)	163 (13.7)	549 (13.6)	
Sitting time (hours/day), mean ± SD	5.5 ± 2.7	4.7 ± 2.4	4.7 ± 2.4	5.0 ± 2.6	4.9 ± 2.5	**<0.001**
Age (years), mean ± SD	33.6 ± 1.4	33.7 ± 1.5	33.7 ± 1.4	34.0 ± 1.4	33.8 ± 1.4	0.863
Weight (kg), mean ± SD	71.1 ± 15.1	71.2 ± 15.4	69.6 ± 15.6	71.8 ± 16.3	70.7 ± 15.7	0.097
BMI (kg/m^2), mean ± SD	25.8 ± 5.2	25.8 ± 5.4	25.2 ± 5.5	26.2 ± 5.9	25.7 ± 5.6	**0.003**
Country of birth						0.137
Australian born	508 (94.6)	544 (91.6)	1753 (93.1)	1200 (94.0)	4005 (93.4)	
Not Australian born	29 (5.4)	50 (8.4)	130 (6.9)	76 (6.0)	285 (6.6)	
Marital status, *n* (%)						**<0.001**
Married/de facto	523 (97.6)	578 (97.3)	1793 (95.3)	1128 (89.0)	4022 (94.0)	
Not married/partnered	13 (2.4)	16 (2.7)	88 (4.7)	139 (11.0)	256 (6.0)	
Number of children, *n* (%)						**<0.001**
1	207 (38.6)	220 (37.0)	634 (33.7)	265 (20.8)	1326 (30.9)	
2	217 (40.4)	241 (40.6)	841 (44.7)	679 (53.2)	1978 (46.1)	
≥3	113 (21.0)	133 (22.4)	408 (21.7)	332 (26.0)	986 (23.0)	
Currently pregnant, *n* (%)						**<0.001**
No	521 (98.1)	570 (96.6)	1507 (81.2)	1147 (90.6)	3745 (88.3)	
Yes	10 (1.9)	20 (3.4)	349 (18.8)	119 (9.4)	498 (11.7)	
Currently breastfeeding, *n* (%)						**<0.001**
No	403 (75.2)	507 (85.6)	1840 (97.7)	1271 (99.8)	4021 (93.8)	
Yes	133 (24.8)	85 (14.4)	43 (2.3)	3 (0.2)	264 (6.2)	
Caesarean birth, *n* (%)						**0.022**
No	388 (76.8)	434 (77.5)	1396 (77.6)	909 (73.0)	3127 (76.1)	
Yes	117 (23.2)	126 (22.5)	402 (22.4)	336 (27.0)	981 (23.9)	
Current smoker, *n* (%)						**<0.001**
No	504 (94.0)	538 (90.7)	1681 (89.4)	1093 (85.8)	3816 (89.1)	
Yes	32 (6.0)	55 (9.3)	200 (10.6)	181 (14.2)	468 (10.9)	
Frequency of alcohol consumption, *n* (%)						**<0.001**
Non-drinker	82 (15.3)	78 (13.2)	268 (14.3)	152 (11.9)	580 (13.6)	
Rare drinker	158 (29.5)	165 (27.9)	480 (25.6)	312 (24.5)	1115 (26.1)	
Low-risk drinker	290 (54.2)	333 (56.4)	1065 (56.8)	747 (58.6)	2435 (56.9)	
Risky/high-risk drinker	5 (0.93)	15 (2.5)	63 (3.4)	64 (5.0)	147 (3.4)	
Education, *n* (%)						**<0.001**
No formal/high school	75 (14.2)	104 (17.8)	372 (20.3)	384 (30.7)	935 (22.3)	
Trade/diploma	124 (23.5)	144 (24.6)	477 (26.0)	377 (30.2)	1122 (26.7)	
Degree or higher	328 (62.2)	338 (57.7)	986 (53.7)	488 (39.1)	2140 (51.0)	
Annual household income, *n* (%)						**0.001**
Low (0–36,399 AUD)	31 (6.2)	40 (7.4)	125 (7.3)	128 (11.2)	324 (8.3)	
Medium (36,400–77,999 AUD)	142 (28.6)	182 (33.7)	536 (31.3)	384 (33.5)	1244 (31.9)	
High (>77,999 AUD)	324 (65.2)	318 (58.9)	1053 (61.4)	634 (55.3)	2329 (59.8)	
Occupation, *n* (%)						**<0.001**
No paid job	221 (41.8)	240 (41.0)	610 (33.1)	300 (24.1)	1371 (32.6)	
Clerical/trade job	28 (5.3)	54 (9.2)	249 (13.5)	307 (24.6)	638 (15.2)	
Associate professional	61 (11.5)	80 (13.7)	281 (15.2)	216 (17.3)	638 (15.2)	
Professional	219 (41.4)	212 (36.2)	705 (38.2)	423 (34.0)	1559 (37.1)	
Currently employed, *n* (%)						**0.015**
No	27 (5.1)	20 (3.4)	113 (6.1)	89 (7.0)	249 (5.9)	
Yes	505 (94.9)	570 (96.6)	1740 (93.9)	1175 (93.0)	3990 (94.1)	
ARIA+						
Major cities of Australia	314 (59.5)	343 (59.0)	1022 (55.3)	561 (44.2)	2240 (53.0)	**<0.001**
Inner regional Australia	132 (25.0)	152 (26.2)	509 (27.5)	430 (33.9)	1223 (28.9)	
Outer regional Australia	66 (12.5)	65 (11.2)	268 (14.5)	222 (17.5)	621 (14.7)	
Remote/very remote Australia	16 (3.0)	21 (3.6)	50 (2.7)	55 (4.3)	142 (3.4)	
Childcare use						**<0.001**
No	212 (39.8)	163 (27.6)	328 (17.5)	240 (18.9)	943 (22.1)	
Yes	321 (60.2)	428 (72.4)	1546 (82.5)	1030 (81.1)	3325 (77.9)	

ARIA+, Accessibility/Remoteness Index of Australia; IQR, interquartile range; PA, physical activity; SD, standard deviation.
Data were analysed by one-way analysis of variance or Kruskal–Wallis test for continuous variables and Chi-squared test for categorical variables and presented as mean ± SD or median ± interquartile range for continuous variables and number (percentages) for categorical variables; Boldface indicates statistical significance ($P < 0.05$).

Table 2
Adjusted regression coefficient (β) and 95% CIs of factors associated with physical activity levels (MET.min/week) in women with young children ($N = 3392$).

Characteristic	[a]Simple model β (95% CI) MET.min/week	*P*-value	[b]Full model β (95% CI) MET.min/week	*P*-value
Age of youngest child				
Infants (0–6 months)	−250.2 (−335.2, −165.3)	**<0.001**	−321.3 (−416.2, −226.4)	**<0.001**
Infants (>6–12 months)	−106.8 (−189.2, −24.4)	**0.011**	−147.9 (−237.6, −58.1)	**0.001**
Toddlers (>12–36 months)	−114.8 (−175.0, −54.6)	**<0.001**	−106.4 (−172.3, −40.5)	**0.002**
Preschoolers (>36–72 months)	Ref	Ref	Ref	Ref
Age (years)	−14.8 (−32.5, 2.9)	0.102	−20.6 (−39.4, −1.8)	**0.032**
BMI (kg/m^2)	−12.6 (−17.1, −8.0)	**<0.001**	−5.8 (−11.0, −0.56)	**0.032**
Marital status				
Married/de facto	Ref	Ref	Ref	Ref
Not married/partnered	154.7 (46.0, 263.5)	**0.005**	148.0 (1.8, 294.2)	**0.047**
Currently pregnant				
No	Ref	Ref	Ref	Ref
Yes	−252.4 (−333.4, −171.4)	**<0.001**	−316.0 (−403.6, −228.4)	**<0.001**
Current smoker				
No	Ref	Ref	Ref	Ref
Yes	−89.0 (−170.9, −7.1)	**0.033**	−54.1 (−148.5, 40.3)	0.261
Frequency of alcohol consumption				
Non-drinker	−145.6 (−222.3, −69.0)	**<0.001**	−44.6 (−128.9, 39.8)	0.300
Rare drinker	−122.2 (−182.2, −62.3)	**<0.001**	−68.9 (−133.9, −4.0)	**0.037**
Low-risk drinker	Ref	Ref	Ref	Ref
Risky/high-risk drinker	−174.4 (−314.1, −34.6)	**0.014**	−115.3 (−266.1, 35.5)	0.134
Education				
No formal education/high school	Ref	Ref	Ref	Ref
Trade/diploma	33.5 (−39.4, 106.3)	0.368	23.9 (−56.6, 104.3)	0.561
Degree or higher	67.5 (2.4, 132.7)	**0.042**	6.1 (−78.3, 90.4)	0.888
Annual household income				
Low (0–36,399 AUD)	Ref	Ref	Ref	Ref
Medium (36,400–77,999 AUD)	35.5 (−65.5, 136.5)	0.491	−2.2 (−115.0, 110.7)	0.970
High (>77,999 AUD)	118.3 (22.2, 214.5)	**0.016**	65.6 (−48.3, 179.6)	0.259
Occupation				
No paid job	Ref	Ref	Ref	Ref
Clerical/trade job	94.6 (13.3, 175.9)	**0.023**	99.7 (10.5, 189.0)	**0.029**
Associate professional	63.1 (−16.6, 142.7)	0.121	−27.0 (−114.1, 60.0)	0.542
Professional	67.0 (5.6, 128.3)	**0.032**	14.6 (−58.8, 88.1)	0.696
Anxiety				
No	Ref	Ref	Ref	Ref
Yes	−85.3 (−136.6, −34.0)	**0.001**	−45.6 (−111.6, 20.4)	0.175
Depression				
No	Ref	Ref	Ref	Ref
Yes	−136.3 (−200.7, −71.8)	**<0.001**	−45.6 (−126.0, 34.7)	0.266
Mean stress level	−23.7 (−72.3, 24.9)	0.339	62.7 (−1.6, 127.0)	0.056
Difficulty sleeping in last 12 months				
Never/rarely	Ref	Ref	Ref	Ref
Sometimes/often	9.1 (−45.3, 63.5)	0.743	49.7 (−11.9, 111.3)	0.114
Self-rated health				
Excellent	489.7 (375.7, 603.7)	**<0.001**	469.1 (331.9, 606.2)	**<0.001**
Very good	341.2 (241.3, 441.1)	**<0.001**	323.1 (204.0, 442.3)	**<0.001**
Good	146.1 (43.3, 248.9)	**0.005**	135.7 (18.8, 252.6)	**0.023**
Fair/poor	Ref	Ref	Ref	Ref
ARIA+				
Major cities of Australia	Ref	Ref	Ref	Ref
Inner regional Australia	−17.5 (−76.9, 42.0)	0.564	11.0 (−52.8, 74.7)	0.736
Outer regional Australia	−18.7 (−94.0, 56.7)	0.627	4.7 (−76.6, 86.0)	0.910
Remote/very remote Australia	−46.2 (−191.4, 98.9)	0.532	13.1 (−140.9, 167.0)	0.868
Childcare use				
No	Ref	Ref	Ref	Ref
Yes	49.3 (−13.2, 111.9)	0.122	19.2 (−50.9, 89.3)	0.591

ARIA+, Accessibility/Remoteness Index of Australia, childcare use; BMI, body mass index; CI, confidence interval; Ref, reference category.
Boldface indicates statistical significance ($P < 0.05$).
[a] Model includes age of youngest child.
[b] Model is additionally adjusted for age, BMI, marital status, current pregnancy status, smoking status, alcohol intake, household income, education, occupation, depression, anxiety, stress, having difficulty sleeping in the last 12 months and self-rated health.

that women who experienced a caesarean birth consult with their health professional before resuming PA.[40]

It must be recognised that the period after childbirth is a time of new responsibilities and competing demands for time that pose barriers to engaging in adequate levels of PA.[13] Therefore, interventions targeting the improvement of PA levels in women with young children need to provide adequate support to overcome these barriers. Previous studies have highlighted the importance of social support, self-efficacy, enjoyment, intentions and outcome expectancies in influencing activity levels of mothers.[13,41,42] In particular, the perception of mothers' roles and social norms associated with negotiating childcare and household chores with their partners influences their PA levels.[43] Interventions to increase activity levels in women with young children should consider a family-based approach to facilitate increase in self-efficacy and social support from partners.[13]

Table 3
Adjusted regression coefficients (β) and 95% CI of factors associated with sitting time (hours/day) in women with young children ($N = 3394$).

Characteristic	[a]Simple model β (95% CI), h/day	*P*-value	[b]Full model β (95% CI), h/day	*P*-value
Age of youngest child				
Infants (0–6 months)	0.50 (0.25, 0.76)	**<0.001**	0.48 (0.19, 0.77)	**0.001**
Infants (>6–12 months)	−0.35 (−0.60, −0.10)	**0.005**	−0.33 (−0.60, −0.05)	**0.019**
Toddlers (>12–36 months)	−0.32 (−0.51, −0.14)	**0.001**	−0.40 (−0.60, −0.20)	**<0.001**
Preschoolers (>36–72 months)	Ref	Ref	Ref	Ref
Age (years)	−0.05 (−0.11, 0.002)	0.058	−0.03 (−0.08, 0.03)	0.388
BMI (kg/m^2)	0.05 (0.03, 0.06)	**<0.001**	0.04 (0.03, 0.06)	**<0.001**
Marital status				
Married/de facto	Ref	Ref	Ref	Ref
Not married/partnered	0.21 (−0.12, 0.54)	0.208	0.25 (−0.19, 0.69)	0.260
Currently breastfeeding				
No	Ref	Ref	Ref	Ref
Yes	−0.69 (−1.03, −0.36)	**<0.001**	−0.26 (−0.61, 0.10)	0.159
Number of children				
1	Ref	Ref	Ref	Ref
2	−0.77 (−0.95, −0.59)	**<0.001**	−0.63 (−0.83, −0.44)	**<0.001**
≥3	−1.2 (−1.5, −1.0)	**<0.001**	−1.0 (−1.2, −0.78)	**<0.001**
Frequency of alcohol consumption				
Non-drinker	0.16 (−0.08, 0.39)	0.188	0.30 (0.05, 0.55)	**0.019**
Rare drinker	0.07 (−0.11, 0.25)	0.450	0.09 (−0.1, 0.29)	0.343
Low-risk drinker	Ref	Ref	Ref	Ref
Risky/high-risk drinker	−0.10 (−0.52, 0.32)	0.636	−0.28 (−0.73, 0.17)	0.216
Household income				
Low (0–36,399 AUD)	Ref	Ref	Ref	Ref
Medium (36,400–77,999 AUD)	0.14 (−0.18, 0.45)	0.393	0.18 (−0.16, 0.52)	0.306
High (>77,999 AUD)	0.57 (0.27, 0.87)	**<0.001**	0.54 (0.19, 0.88)	**0.002**
Occupation				
No paid job	Ref	Ref	Ref	Ref
Clerical/trade job	0.55 (0.30, 0.79)	**<0.001**	0.46 (0.19, 0.72)	**0.001**
Associate professional	1.1 (0.87, 1.4)	**<0.001**	0.88 (0.62, 1.1)	**<0.001**
Professional	0.76 (0.58, 0.94)	**<0.001**	0.55 (0.34, 0.76)	**<0.001**
Anxiety				
No	Ref	Ref	Ref	Ref
	0.30 (0.14, 0.45)	**<0.001**	0.05 (−0.15, 0.25)	0.613
No	Ref	Ref	Ref	Ref
Yes	0.36 (0.16, 0.56)	**<0.001**	0.01 (−0.23, 0.25)	0.933
Mean stress level	0.47 (0.32, 0.62)	**<0.001**	0.29 (0.10, 0.49)	**0.003**
Difficulty sleeping in last 12 months				
Never/rarely	Ref	Ref	Ref	Ref
Sometimes/often	0.16 (−0.01, 0.32)	0.059	0.06 (−0.12, 0.24)	0.521
Self-rated health				
Excellent	−0.69 (−1.0, −0.34)	**<0.001**	−0.36 (−0.77, 0.05)	0.087
Very good	−0.49 (−0.80, −0.18)	**0.002**	−0.29 (−0.65, 0.07)	0.114
Good	−0.19 (−0.51, 0.12)	0.232	−0.08 (−0.43, 0.27)	0.646
Fair/poor	Ref	Ref	Ref	Ref
ARIA+				
Major cities of Australia	Ref	Ref	Ref	Ref
Inner regional Australia	−0.20 (−0.38, −0.03)	**0.026**	−0.07 (−0.26, 0.12)	0.464
Outer regional Australia	−0.45 (−0.68, −0.22)	**<0.001**	−0.33 (−0.57, −0.09)	**0.008**
Remote/very remote Australia	−0.44 (−0.87, −0.01)	**0.047**	−0.20 (−0.67, 0.26)	0.387
Childcare use				
No	Ref	Ref	Ref	Ref
Yes	0.12 (−0.07, 0.30)	0.227	−0.10 (−0.31, 0.12)	0.378

ARIA+, Accessibility/Remoteness Index of Australia, childcare use; BMI, body mass index; CI, confidence interval; Ref, reference category.
Boldface indicates statistical significance ($P < 0.05$).
[a] Model includes age of youngest child.
[b] Model is additionally adjusted for age, BMI, number of children, currently breastfeeding, alcohol intake, household income, occupation, anxiety, depression, stress, having difficulty sleeping in last the 12 months and self-rated health.

We observed a very small decrease in levels of PA with increasing age of women, even in this cohort in which the age range was only 5 years. This is consistent with evidence of decline in PA with age.[44] In our study, being pregnant was associated with PA levels that were lower by 316 MET.min/week (equivalent to 1.6 h/week less PA) than in those who were not pregnant. This is not surprising, given reports of decrease in PA during pregnancy because of concerns about foetal well-being, changing body shape and fatigue.[3,10] Our finding of higher levels of PA in single women than in women with partners is consistent with some previous reports,[15,45] but not all.[46] Our finding agrees with previous reports that married women have less discretionary time than single women,[15] but it is possible that mothers without a partner share parental responsibilities with the child's father, giving the mothers some time for self-care. We found that women who rarely drank had lower levels of PA than low-risk drinkers. This is consistent with previous studies, which show a positive correlation between alcohol intake and PA in women.[47,48] Low-risk drinking may reflect higher socio-economic status, for example, the consumption of wine with dinners.[49] Previous research suggests that affluent individuals are more prone to combine drinking with positive health behaviours.[49] Consistent with our findings, a positive association between PA and self-rated health has previously been reported.[50,51] Women who perceive themselves as having poorer health may

have underlying health conditions that could have contributed to their low PA levels. The association is likely bidirectional, as better self-rated health may result in engaging in more PA and engaging in more PA may result in better self-rated health.[51]

We observed that women whose youngest child was an infant aged 0–6 months reported higher ST than those whose youngest child was a preschooler. A potential explanation for this is that women incur the greatest responsibility of care at this life stage[25] and infants aged 0–6 months require frequent feeding, which is usually done while sitting. Women whose youngest child was an infant aged >6–12 months or a toddler reported lower ST than those whose youngest child was a preschooler. This represents a time when the child is increasingly mobile, which may increase mothers' activities relating to their care, thereby contributing to a decrease in ST.[14] We observed that women with more children reported lower ST, which is consistent with previous reports of associations of low ST with higher parity.[24,52] This potentially relates to increase in household caregiving activities with increase in the number of children at home.[14,23]

There was a small positive association between BMI and ST, as has been shown in previous studies.[53–55] This association is likely to be bidirectional, with increases in weight resulting in more ST and increases in ST resulting in increased weight.[56] We found that women with high income reported higher ST than women with low income, consistent with reports of a positive association between ST and income.[57] Having a job was also associated with reporting higher ST than having no job, which may be explained by work-related sitting. Both these findings suggest that higher socio-economic status was associated with higher ST. This may reflect more sedentary-type work and access to childcare, potentially contributing to high ST. Evidence suggests that ST in one segment of life correlates with ST in other segments of life, thereby women with sedentary-type jobs may also engage in sedentary leisure-time activities.[57,58] We found that women who were more stressed reported higher ST. A possible explanation for this is that mothers who experience parenting stress may use television watching, usually done while sitting, to cope with stress.[59,60] Interventions to reduce ST in women with young children could therefore include strategies to deal with stress.

Strengths and limitations

The strength of our study is the large population-based sample. The main limitation is the cross-sectional design, which precludes the assessment of prepregnancy measures and of causal relationships. It was not possible to examine associations longitudinally because surveys were repeated every 3 years with multiple births occurring between surveys. However, in agreement with our findings, recent longitudinal analyses of data from women in the same ALSWH cohort provided evidence of changes in levels of PA and ST in women after having children.[24] Future longitudinal studies should explore how levels of PA and ST in women may be influenced by the age of children. Another limitation is attrition over time in ALSWH, which makes the current analysis sample less representative of the general population than at the commencement of the cohort. Furthermore, the measures of PA and ST were self-reported. The use of objective measures was not feasible due to financial and logistic constraints; however, the measures have been shown to have acceptable psychometric properties.[30,61]

Conclusions

Compared with women whose youngest child was a preschooler, women with an infant under 1 year were less likely to meet PA recommendations, and women with an infant under 6 months were more likely to sit more. On the other hand, women whose youngest child was a toddler were more likely to sit less. Different sociodemographic and behavioural factors were associated with PA and ST and reflect the events in women's lives at this life stage. We demonstrate that levels of PA and ST differ among women with infants, toddlers and preschoolers. Our findings provide evidence to support the identification of women at increased risk based on their characteristics and inform intervention development to adequately support women through this life stage.

Author statements

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Ethical approval

The study was approved by the Ethics Committees of the University of Newcastle (h-076-0795) and the University of Queensland (200400224) Australia.

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Competing interests

No conflict of interest was declared by the authors of this article.

Data availability

ALSWH survey data are owned by the Australian Government Department of Health and due to the personal nature of the data collected, release by ALSWH is subject to strict contractual and ethical restrictions. Ethical review of ALSWH is by the Human Research Ethics Committees at the University of Queensland and the University of Newcastle. De-identified data are available to collaborating researchers where a formal request to make use of the material has been approved by the ALSWH Data Access Committee. The committee is receptive of requests for data sets required to replicate results. Information on applying for ALSWH data is available from https://alswh.org.au/for-data-users/applying-for-data/

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.10.016.

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Original Research

Multidimensional housing insecurity and psychological health: how do gender and initial psychological health differentiate the association?

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ABSTRACT

Objectives: Despite compelling evidence for housing-health associations, it is still unclear (1) whether gender differentiates psychological responses to housing insecurity and (2) the extent to which initial psychological health influences the association between housing insecurity and psychological health. The present study aims to reduce these knowledge gaps.
Study design: We used data from over 13 waves (155,114 observations) of the Korea Welfare Panel Study.
Methods: This study tests fixed effects models that can take into account measured and unmeasured heterogeneity. Quantile regression with fixed effects was conducted to assess whether the observed association depends on the initial state of psychological health. All analyses are gender stratified.
Results: Fixed effects estimates show that housing problems, such as being a renter ($b = 0.159$), housing cost burden ($b = 0.173$), and rental/or mortgage arrears ($b = 1.194$), are significantly associated with depressive symptoms. Similar patterns were observed for poor housing quality ($b = 0.598$) and a lack of essential facilities ($b = 0.286$). Although the association between the severity of housing insecurity and depressive symptoms was concentrated among men with initially higher levels of depressive symptoms, the observed association was consistently pronounced for women regardless of initial psychological health.
Conclusions: This study suggests that gender perspectives need to be incorporated into the development of housing intervention for vulnerable groups.

Introduction

Housing insecurity refers to limited access to adequate, affordable, and secure housing and is often interchangeably used with housing disadvantage, housing precarity, and housing instability. Extensive evidence suggests that housing insecurity has an adverse impact on residents' health. Substandard dwelling conditions deteriorate one's health by rapidly increasing the spread of infectious diseases and deteriorating the quality of life.[1–3] Also, renters are less likely to enjoy health benefits, compared with homeowners, from a sense of comfort and belongingness attached to the housing they occupy.[4] Moreover, housing cost burdens contribute to psychological and physical health problems by the reduced disposable income for necessities and amenities (e.g. food and health care) and causing immediate stressors.[5] This evidence bolsters the case for identifying how and whether housing insecurity poses a threat to health.

However, what is understudied is how multiple dimensions of housing insecurity affect health outcomes concurrently. The literature has asserted that housing insecurity is a multidimensional concept that can be categorized into housing quality, affordability, and tenure security.[6–8] Studies along this line of literature have shown that some people experience only a single dimension of housing insecurity, whereas others simultaneously suffer multiple dimensions of insecurity.[9] Most of the prior research has, however, tended to look into the effect of a single dimension of housing insecurity on health and yielded an incomplete conceptual understanding of housing insecurity.[7,10] This indicates that using a single measure of housing problems may not be able to capture the

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breadth and severity of housing insecurity and its impact on health outcomes accurately. Therefore, the examination of the concurrent influences of multiple dimensions of housing insecurity would allow us to identify who is at greater health risk of housing insecurity and how the co-occurrence of different dimensions of housing insecurity deteriorates health.

Interestingly, the *gender* lens shows the ways in which men and women show heterogenous psychological responses to housing insecurity.[11] One of the reasons for the gender difference is that men and women interpret and behave toward housing issues in a different manner.[11,12] First, women tend to be more sensitive to the physical and social environment of their residence (e.g. home, community) than men do.[13,14] This is related to the fact that women are more likely to associate a place with relational comfort because they are able to maintain social relations with family and friends at home.[15] Second, given that women are more likely to be burdened with and psychologically overwhelmed by caregiving and housework, their health tends to be more subject to housing conditions (e.g. hygiene of restroom and kitchen) and associate their homes with well-being and the sense of belonging, compared with men.[16] In addition, disproportionate victimization by violence and crime influences women to seek comfort and safety in living spaces for their well-being and survival.[17] In adequate housing conditions, not only can women feel protected from external stressors (e.g. noise), but they can also rebuild their personal life, such as rest and building healthy routines. On the other hand, men may display lower levels of psychological responses to housing insecurity. Men are reluctant to associate their feelings with economic circumstances because the emotional attachment to their economic conditions may weaken the image of masculinity that men value.[18] Rather than displaying negative feelings, they tend to show externalizing behaviors (e.g. drinking and smoking) in response to stressors, such as housing insecurity.[19] A combination of such conditions suggests that women, more than men, may seek positive meaning and psychological comforts from their housing.

Psychological resources help people to mitigate their concerns about threatening life situations. Given that psychological vulnerability sensitizes one's coping strategies (e.g. worries over being judged as a burden by others),[20] people with long-standing vulnerability (e.g. prolonged depressive symptoms) may not be able to cope properly with financial difficulties and excessively internalize their concerns.[21] Moreover, one's strong tendency to maintain autonomy and mental health can buffer against stressful events.[22] This corresponds to the notion of *psychological resilience* that helps people to return to prestressor status quickly.[23] Reflecting on these explanations, empirical studies have demonstrated that the negative health effects of stressors, such as unemployment,[24,25] tend to be concentrated among those with pre-existing health problems. However, a limited number of studies have taken into account the heterogeneous health effects of housing problems considering a person's initial health. Although one study showed that individuals with poorer initial mental health were more adversely affected by unaffordable housing,[26] it did not identify the effect of multiple dimensions of housing insecurity on mental health.

To fill these research gaps, this study aims to assess the extent to which multidimensional housing insecurity affects psychological health among Korean adults aged ≥20 years. Despite the government's increased efforts to implement a range of housing assistance programs, many low-income households currently face various housing difficulties in Korea.[9] Not only do people find it challenging to afford housing expenses in the expensive housing market but also some disadvantaged groups live in poor dwelling conditions not equipped with essential facilities.[27] These housing problems are likely to have detrimental effects on vulnerable groups' health in Korea. In this study, we assess (1) whether there is a gendered association between multiple dimensions of housing insecurity and psychological health and (2) whether a person's initial psychological health conditions influence the effects of housing insecurity on psychological health. The findings of this study contribute to designing housing intervention and care services for vulnerable groups suffering from housing insecurity.

Methods

Data

This study uses data from the Korea Welfare Panel Study (KoWEPS), one of the nationally representative longitudinal studies. Since it was co-launched by the Korea Institute for Health and Social Affairs and Seoul National University in 2006, it annually collects information (e.g. socio-economic status, health, and welfare needs) through in-person interviews (18,856 individuals from 7072 households at Wave 1). Survey participants were sampled through stratified double sampling based on the National Living Conditions Study of 2006, representing 90% of the census conducted in 2005. The present study used data from Wave 3 (2007) to Wave 15 (2019). Wave 1 to Wave 2 was not used because the survey in those waves did not include information related to housing problems. After deleting missing variables (9988 observations, attrition rate: 6%), the sample is restricted to adults aged ≥20 years (155,114 observations). Ethical approval was exempted from a full review by the institutional review board because the present study relies on secondary analysis of publicly available data (https://www.koweps.re.kr:442/eng/main.do).

Measures

Independent variable

The primary independent variable is housing insecurity. Drawing on Clair et al. and Routhier (2019), we extracted five dimensions of housing insecurity from the data set: (1) tenure, (2) housing cost burden, (3) rent/or mortgage arrear, (4) poor housing quality, and (5) limited access to essential facilities. First, the participants were asked to answer the following question: “what was your housing tenure as of the 31st Dec last year?” We categorized the responses into either 1 (public and private renters) or 0 (owner-occupiers, including mortgagors). Second, housing cost burden was calculated from housing expenses (e.g. rents, mortgage, interest, and utility) and household income (e.g. earnings, cash transfers, etc.). In accordance with the normative standard of housing unaffordability in the housing literature,[28] we define housing cost burden if a household pays more than 30% of the household income for housing expenses. Third, for housing arrears, renters who reported they had ever been behind on rent and homeowners who responded they had been behind on mortgage repayment during the past year. Fourth, we established a dichotomous variable of the quality of housing if the housing was below any of the following housing standards: structurally safe and built with adequate materials for fire and heat resistance; adequate moisture proof, ventilation, and lighting; protected from noise, odor, and air pollution; protected from natural disasters; and equipped with safe electrical and evacuation facility. Last but not least, we established a dichotomous variable for the adequacy of essential facilities at home (e.g. having an independent flush toilet/independent standing kitchen; 1 = no access, 0 = have access). After aggregating these five dimensions of housing insecurity, the scale ranges from 0 (not insecure) to 5 (most insecure).

Dependent variable

Depressive symptoms were measured with 11 questions from the Center for Epidemiologic Studies Depression (CES-D) scale. The measure was validated and widely used in public health studies.[29] It includes the following questions: (1) I did not feel like eating, and my appetite was poor; (2) I felt that I was doing generally well; (3) I felt depressed; (4) I had trouble keeping my mind on what I was doing; (5) I could not sleep well; (6) I felt lonely; (7) I went on without any complaints; (8) I felt that people were treating me coldly; (9) I felt sad (10) I felt that people disliked me; and (11) I was unable to have the courage to carry out something. The study participants were required to choose responses ranging from 0 (very rare or less than a day) to 3 (almost all the time or more than 5 days). These responses were then combined into total scores after reversely coding the two items (2) and (7), whereby a higher score indicates a higher level of depressive symptoms. Given that psychological health used for this study is a continuous variable (ranging from 0 to 33), its distribution allows the method from a statistical perspective.

Control variable

We adjusted for a series of control variables, age (continuous), age-squared (continuous), marital status, number of household members, educational attainment, household income, economic activity, place of residence, and the presence of chronic disease. Marital status was measured in terms of whether the respondent was single, married, or widowed/divorced/separated. The number of household members was categorized into one person, two or three persons, and four persons or over. Educational attainment was categorized into junior-high school or lower, high school graduate, and college graduate or higher. Household income was log-transformed. Economic activity was measured by whether the respondent was a regular worker, temporary worker, self-employed (including unpaid workers), or unemployed/economically inactive. Place of residence was categorized into large cities (with at least 1,000,000 population), small cities (with fewer than 1,000,000 population), and rural areas (with a population of less than 100,000). The presence of chronic disease refers to whether the respondents had a chronic disease.

Statistical analysis

First, this study uses fixed effects models to account for observed and unobserved individual-level heterogeneity that might jointly affect housing problems and health. This is important because the failure to take into individual-level heterogeneity may over- or under-estimate the observed association. For example, health outcomes may be shaped not only by the housing problems *per se* but also by the characteristics of those who experience housing insecurity (e.g. lower income).[30] In addition, we cannot rule out the possibility that some factors (e.g. employment status) are concurrently related to housing insecurity and health. Therefore, to estimate the housing-health link accurately, it requires rigorous methods that can detect changes in the levels of depressive symptoms and also account for confounding effects. The coefficient estimated from the models indicates variation within individuals whose psychological health is changed by the occurrence of housing problems at different time points. Next, we include an interaction term of housing problems and gender in a fixed effects model to assess gender differences.

Second, we assume that the negative effects of housing insecurity on psychological health could be dependent on the initial levels of psychological health. Therefore, we use quantile regression to assess the association between housing insecurity and health at each decile of the outcome variables. Quantile regression models were conducted for the 10th, 50th, and 90th percentiles: the 0.1 and 0.9 quantile regression estimates the lower (those with lower levels of depressive symptoms in the baseline) and upper part of the distribution (those who have higher levels of depressive symptoms), respectively. The 0.5 quantile regression models show the effects of housing security on the median of the outcome distribution (moderate level). Statistical analyses were performed in Stata SE version 17 (StataCorp, College Station, TX, USA).

Results

Table 1 shows the summary statistics for all the observations of the individuals between 2007 and 2019. In the total sample, 38.1% reported being renters, and 13.6% reported housing cost burden. This is similar to Korea's housing conditions, revealing that about 40% of households are renters and 11% of households are housing cost burdened.[31] In addition, while 1.1% responded being behind on rent/mortgage payments, one-fifth of the sample suffered poor-quality housing, and 4.8% reported not having access to essential facilities. Meanwhile, about 32% were found to experience two housing insecurity problems, and about 4.5% reported that they had more than three housing problems. The average CES-D score was 3.964. About 64.2% of the participants were married, and about half of the participants had two or three household members. Overall, 40.0% were in higher school or less educated. On average, 42.3% lived in a large city. Compared with men, women had a higher number of housing problems, a higher score of CES-D, and a lower level of education.

Table 2 presents the results from the fixed effects model that estimates the association between each of the five dimensions of housing insecurity and depressive symptoms: housing tenure (from homeowners to renters; $b = 0.159$ in Column 1), housing cost burden ($b = 0.173$ in Column 2), being behind on rent/or mortgage payment ($b = 1.194$ in Column 3), poor housing quality ($b = 0.598$ in Column 4), and lower access to essential facilities of dwellings ($b = 0.286$ in Column 5). The five dimensions of housing insecurity were all significantly associated with a higher level of depressive symptoms.

Table 3 presents the association between the severity of housing insecurity problems experienced by the respondents (i.e. how many dimensions of housing insecurity the respondents experienced) and depressive symptoms. We found that as the number of housing problems increased, the likelihood of depressive symptoms also increased ($b = 0.376$ for one, $b = 0.547$ for two, and $b = 1.208$ for more than three problems in Column 1). Such effects are equivalent to income ($b = -0.478$). The results from the gender-stratified analyses show that the observed association is pronounced among women compared with men. Although both men and women showed psychological responses to the severity of housing insecurity, the magnitude of depressive symptoms tends to be steeper for women ($b = 0.408$ for one, $b = 0.619$ for two, and $b = 1.396$ for more than three problems in Column 3) compared with men ($b = 0.269$ for one, $b = 0.425$ for two, and $b = 0.910$ for more than three problems in Column 2). These gender differences are statistically significant in the interaction term of gender and housing insecurity, as presented in Column 4.

Table 4 summarizes the results of gender-stratified quantile treatment effect regression. While the severity of housing insecurity was not significantly associated with depressive symptoms for men with initial low (0.1 quantiles in Column 1) and moderate levels of depressive symptoms (0.5 quantiles in Column 2), the likelihood was concentrated among men with moderate-higher levels of depressive symptoms ($b = 0.225$ for one, $b = 0.355$ for two, $b = 0.769$ for more than three housing insecurity in Column 2) and initial higher levels of depressive

Table 1
Descriptive Statistics, KoWEPS (2007–2019).

Characteristics	Total	Men	Women	Gender diff
	Prop./*mean*	Prop./*mean*	Prop./*mean*	*P*-value
Independent variable				
Housing insecurity				
Renting	0.381	0.356	0.400	*
Housing cost burden	0.136	0.117	0.151	*
Behind on rents/mortgage repayments	0.011	0.012	0.011	
Poor housing quality	0.206	0.200	0.210	*
Inadequacy of essential facilities	0.048	0.043	0.051	*
Severity of housing insecurity (i.e. number of housing problems)				*
0	0.477	0.501	0.459	
1	0.319	0.320	0.319	
2	0.158	0.140	0.173	
3+	0.045	0.040	0.049	
Dependent variables				
Depressive symptoms (CES-D)	3.964	3.199	4.552	*
Control variables				
Age	54.598	52.862	55.403	
Marital status				*
Single	0.145	0.180	0.117	
Married	0.642	0.723	0.580	
Divorced/separated/widowed	0.214	0.098	0.303	
Number of household members				*
One	0.153	0.087	0.204	
Two or three	0.521	0.565	0.487	
Four and over	0.326	0.348	0.309	
Educational attainment				*
Middle school or less	0.303	0.186	0.393	
High school graduate	0.400	0.451	0.360	
College or higher	0.298	0.363	0.247	
Logged household income (Korean Won)	7.518	7.599	7.457	*
Economic activity				*
Regular worker	0.200	0.295	0.128	
Temporary worker	0.187	0.178	0.194	
Self-employed	0.197	0.240	0.164	
Unemployed/economically inactive	0.416	0.287	0.515	
Place of residence				*
Large cities	0.423	0.426	0.421	
Small cities	0.364	0.370	0.360	
Rural areas	0.213	0.204	0.219	
The presence of chronic disease				*
No	0.457	0.508	0.418	
Yes	0.543	0.493	0.582	
N (observations)	155,114	67,424	87,690	

Prop = proportion. Chi-squared tests for categorical variables and *t*-test for continuous variables were performed. *Difference between men and women are statistically significant, $P < 0.05$.

symptoms ($b = 1.608$ for more than three problems in Column 3). In contrast, the quantile treatment regression provides different results for women. Although only suffering more than three dimensions of housing insecurity significantly predicted the likelihood of reporting depressive symptoms for women with initial lower levels of depressive symptoms ($b = 1.254$ in Column 1), the experience of greater severity of housing insecurity predicted increased levels of depressive symptoms for women with initial moderate ($b = 0.367$ for one, $b = 0.562$ for two, $b = 1.254$ for more than three housing insecurity in Column 6) and with initially higher levels of depressive symptoms ($b = 0.645$ for one, $b = 0.952$ for two, $b = 2.224$ for more than three housing insecurity in Column 6).

Discussion

Despite a growing body of evidence on the association between housing and health, it is still unclear (1) how multiple dimensions of housing insecurity influence health concurrently, (2) whether gender differentiates the association between housing insecurity and health, and (3) how psychological responses to housing insecurity are affected by initial conditions of psychological health. This study aims to reduce these knowledge gaps.

We found that housing insecurity leads to a higher level of depressive symptoms in Korea regardless of the type of housing problem. Our finding strengthens the validity of the prior literature that examined the effect of selected dimensions of housing insecurity on health.[9,32] What is more interesting is that depressive symptoms are disproportionately influenced by the increasing number of housing insecurity problems. This implies that the co-occurrence of multiple dimensions of housing insecurity has a far more detrimental effect on psychological health compared with the occurrence of a single dimension of housing insecurity. This study revisits the dose–response relationship where an elevated level of exposure to risks predicts increasing risks of poor health outcomes.[33] Also, it affirms that multidimensional indicators are essential to measuring housing insecurity for fully grasping its impact on psychological health.

Second, there is a gendered association between housing insecurity and depressive symptoms. Men are responsive to the health effects of housing problems only when having higher levels of depressive symptoms initially. This result indicates that men's pre-

Table 2
Fixed effects models regressing depressive symptoms on different dimensions of housing insecurity.

	(1)	(2)	(3)	(4)	(5)
	CES-D	CES-D	CES-D	CES-D	CES-D
Types of housing insecurity	Renting	Housing cost burden	Behind on rents/mortgage	Poor quality of housing	Inadequacy of essential facilities
Outcome	CES-D	CES-D	CES-D	CES-D	CES-D
Group	Total	Total	Total	Total	Total
Year fixed effects	Yes	Yes	Yes	Yes	Yes
	B (95% CI)	B (95% CI)	B (95% CI)	B (95% CI)	B (95% CI)
Housing insecurity	0.159*** (0.074, 0.024)	0.173*** (0.084, 0.262)	1.194*** (0.091, 1.478)	0.598*** (0.535, 0.662)	0.286** (0.113, 0.459)
Age	−0.183*** (−0.211, −0.156)	−0.187*** (−0.214, −0.160)	−0.185*** (−0.212, −0.158)	−0.176*** (−0.204, −0.149)	−0.190*** (−0.278, −0.163)
Age square	0.002*** (0.001, 0.001)	0.001*** (0.001, 0.001)	0.001*** (0.001, 0.001)	0.001*** (0.001, 0.001)	0.001*** (0.001, 0.001)
Marital status (ref: single)					
Married	0.160 (−0.050, 0.370)	0.177 (−0.032, 0.387)	0.187 (−0.022, 0.398)	0.196 (−0.014, 0.406)	0.193 (−0.017, 0.402)
Divorced/separated/widowed	0.146 (−0.153, 0.446)	0.157 (−0.142, 0.456)	0.172 (−0.127, 0.471)	0.169 (−0.129, 0.466)	0.176 (−0.123, 0.474)
Number of household members (ref: one)					
Two or three	−0.069 (−0.257, 0.119)	−0.083 (−0.270, 0.104)	−0.105 (−0.291, 0.082)	−0.113 (−0.599, 0.073)	−0.104 (−0.291, 0.083)
Four and over	−0.049 (−0.249, 0.150)	−0.074 (−0.271, 0.124)	−0.099 (−0.297, 0.098)	−0.103 (−0.299, 0.094)	−0.098 (−0.295, 0.099)
Educational attainment (ref: Middle school)					
High school graduate	0.142 (−0.477, 0.763)	0.135 (−0.486, 0.755)	0.157 (−0.461, 0.775)	0.141 (−0.479, 0.762)	0.141 (−0.479, 0.761)
College or higher	0.516 (−0.219, 1.245)	0.510 (−0.222, 1.243)	0.526 (−0.203, 1.256)	0.549 (−0.182, 1.281)	0.510 (−0.222, 1.241)
Logged household income (Korean Won)	−0.478*** (−0.545, −0.410)	−0.468*** (−0.537, −0.401)	−0.468*** (−0.536, −0.401)	−0.482*** (−0.550, −0.415)	−0.475*** (−0.543, −0.408)
Economic activity (ref: regular workers)					
Temporary worker	−0.045 (−0.135, 0.045)	−0.047 (−0.137, 0.043)	−0.049 (−0.139, 0.041)	−0.057 (−0.147, 0.033)	−0.049 (−0.139, 0.041)
Self-employed	−0.019 (−0.141, 0.104)	−0.022 (−0.145, 0.100)	−0.026 (−0.148, 0.096)	−0.030 (−0.152, 0.092)	−0.028 (−0.151, 0.093)
Unemployed/economically inactive	0.313*** (0.215, 0.411)	0.309*** (0.210, 0.407)	0.307*** (0.209, 0.406)	0.307*** (0.209, 0.405)	0.309*** (0.211, 0.408)
Place of residence (ref: large cities)					
Small cities	−0.149 (−0.322, 0.023)	−0.157 (−0.330, 0.016)	−0.155 (−0.328, 0.017)	−0.128 (−0.301, 0.044)	−0.160 (−0.333, 0.126)
Rural areas	−0.355** (−0.583, −0.127)	−0.382** (−0.610, −0.153)	−0.364** (−0.592, −0.137)	−0.347** (−0.573, −0.120)	−0.380** (−0.608, −0.152)
The presence of chronic disease (ref: no)					
Yes	0.369*** (0.308, 0.429)	0.370*** (0.310, 0.431)	0.368*** (0.307, 0.428)	0.355*** (0.295, 0.416)	0.370*** (0.309, 0.430)
Observations	155,114	155,114	155,114	155,114	155,114
N	19,323	19,323	19,323	19,323	19,323

CES-D, Center for Epidemiologic Studies Depression Scale; 95% CI, 95% confidence interval.
Robust standard errors were used.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

Table 3
Fixed effects models regressing depressive symptoms on the severity of housing insecurity.

	(1)	(2)	(3)
Outcome	CES-D	CES-D	CES-D
Group	Total	Men	Women
Year fixed effects	Yes	Yes	Yes
	B (95% CI)	B (95% CI)	B (95% CI)
Number of housing insecurity dimensions (ref: none)			
1	0.376*** (0.286, 0.407)	0.269*** (0.186, 0.352)	0.408*** (0.321, 0.494)
2	0.547*** (0.448, 0.626)	0.425*** (0.296, 0.555)	0.619*** (0.498, 0.741)
3+	1.208*** (1.039, 1.376)	0.910*** (0.660, 1.160)	1.396*** (1.171, 1.620)
Age	−0.170*** (−0.318, 0.028)	−0.185*** (−0.224, −0.145)	−0.169*** (−0.207, −0.132)
Age square	0.001*** (0.001, 0.001)	0.001*** (0.001, 0.002)	0.001*** (0.001, 0.001)
Marital status (ref: single)			
Married	0.124 (−0.085, 0.335)	0.017 (−0.253, 0.289)	0.278 (−0.045, 0.603)
Divorced/separated/widowed	0.115 (−0.183, 0.413)	0.561* (0.110, 1.013)	0.077 (−0.340, 0.493)
Number of household members (ref: one)			
Two or three	−0.003 (−0.190, 0.183)	−0.229 (−0.522, 0.064)	0.094 (−0.145, 0.333)
Four and over	0.040 (−0.158, 0.237)	−0.107 (−0.409, 0.195)	0.087 (−0.173, 0.346)
Educational attainment (ref: middle school)			
High school graduate	0.144 (−0.481, 0.770)	0.548 (−0.408, 1.506)	−0.138 (−0.959, 0.683)
College or higher	0.519 (−0.216.1.254)	0.939 (−0.194, 2.073)	0.248 (−0.712, 1.209)
Logged household income (KRW)	−0.450*** (−0.517, 0.382)	−0.377*** (−0.473, −0.282)	−0.506*** (−0.600, −0.412)
Economic activity (ref: regular workers)			
Temporary worker	−0.047 (−0.137, 0.043)	−0.042 (−0.169, 0.083)	−0.076 (−0.206, 0.053)
Self-employed	−0.013 (−0.35, 0.109)	−0.042 (−0.204, 0.119)	−0.029 (−0.216, 0.155)
Unemployed/economically inactive	0.316*** (0.218, 0.417)	0.549*** (0.396, 0.703)	0.157* (0.023, 0.290)
Place of residence (ref: large cities)			
Small cities	−0.415 (−0.318, 0.028)	−0.164 (−0.400, 0.071)	−0.125 (−0.372, 0.121)
Rural areas	−0.366** (−0.594, −0.139)	−0.322* (−0.636, −0.008)	−0.395* (−0.714, −0.076)
The presence of chronic disease (ref: no)			
Yes	0.359*** (0.299, 0.420)	0.321*** (0.241, 0.400)	0.378*** (0.288, 0.468)
Observations	155,114	67,424	87,690
N	19,323	8788	10,535

CES-D, Center for Epidemiologic Studies Depression Scale; 95% CI, 95% confidence interval.
Robust standard errors were used.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

existing psychological resources play an important role in preventing psychological concerns over housing conditions. Not only are men reluctant to attach feelings to housing insecurity, possibly due to masculinity, but their initial psychological health also helps them to find out resources that alleviate housing insecurity. In contrast, housing insecurity was consistently related to poor psychological health among women, regardless of the initial conditions of their psychological health. This result suggests that women's initial psychological resources cannot fully mitigate adverse consequences predicted by housing problems. Put differently, women's psychological health is more vulnerable to housing problems compared with men's. A possible explanation for this result might be that women tend to associate themselves with their homes more than men do. For example, differential exposures to extreme external stressors, such as crime and violence, may lead women to strongly seek to be safe in their housing.[17] Moreover, women's gendered roles as family caretakers may render them more emotionally attached to their homes. Women may feel more threatened and frustrated by losing a comfortable place or not being able to keep living standards.[16]

This study should be acknowledged in light of its limitations. First, this study could not test the potential mechanisms by which housing insecurity influences psychological health. It was partly due to a lack of information for potential mediators (e.g. gender-specific contribution to housework). Future studies examining underlying mechanisms can deepen our understanding of how housing insecurity impacts health. Second, although housing insecurity may precede depressive symptoms, we cannot completely rule out the reverse causation that psychological health problems can lead to housing insecurity. Robust statistical approaches can help to develop causation models for housing and health.

Despite these limitations, this study has several strengths. This research is one of the few studies that assessed the relationship between housing insecurity and health from a gender perspective. Furthermore, we demonstrated heterogeneous effects of housing problems on psychological health depending on the initial psychological state. The study also explored the health impact of multiple dimensions of housing insecurity, namely, tenure, affordability, housing arrears, quality of dwelling conditions, and essential facilities, in contrast to prior studies mainly focusing on a single dimension of housing insecurity. Our finding lays the foundation for understanding the complexity of housing security that can concurrently occur. Last but not least, we addressed a methodological challenge observed in prior studies by conducting a fixed effects method that controls for measured and unmeasured heterogeneity in the link between housing and health.

These findings have important policy implications in the Korean context. First, even without considering being a renter as a severe housing problem, many households still suffer housing cost burden or/and poor housing quality. It indicates that a large population is subject to psychological health problems. In Korea, diverse housing subsidies, such as public housing and housing benefit, are provided to alleviate low-income households' housing insecurity problems. Designing and implementing housing subsidy programs should be more sensitive to the different psychological impacts of different housing problems, particularly reflecting the critical health impact of poor housing quality and inadequacy of essential facilities at

Table 4
Quantile treatment effect models regressing depressive symptoms on the severity of housing insecurity.

	(1)	(2)	(3)	(4)	(5)	(6)
	CES-D	CES-D	CES-D	CES-D	CES-D	CES-D
Gender	Men	Men	Men	Women	Women	Women
Sample	0.1 quantile	0.5 quantile	0.9 quantile	0.1 quantile	0.5 quantile	0.9 quantile
	B (95% CI)	B (95% CI)	B (95% CI)	B (95% CI)	B (95% CI)	B (95% CI)
Number of housing insecurity dimensions (ref: none)						
1	0.123 (−0.048, 0.300)	0.225** (0.084, 0.366)	0.488 (−0.038, 1.012)	0.233*** (0.114, 0.352)	0.367*** (0.286, 0.449)	0.645*** (0.443, 0.848)
2	0.196 (−0.070, 0.463)	0.355** (0.141, 0.570)	0.772 (−0.028, 1.572)	0.375*** (0.207, 0.543)	0.562*** (0.447, 0.678)	0.952*** (0.666, 1.238)
3+	0.450 (−0.065, 0.965)	0.769*** (0.355, 1.183)	1.608* (0.062, 3.153)	0.788*** (0.479, 1.097)	1.254*** (1.042, 1.466)	2.224*** (1.698, 2.751)

CES-D, Center for Epidemiologic Studies Depression Scale; 95% CI, 95% confidence interval.
Robust standard errors were used. Control variables include age, age square, marital status, number of households, educational attainment, household income, economic activity, place of residence, the presence of chronic disease, and year fixed effects.
$*P < 0.05$; $**P < 0.01$; $***P < 0.001$.

home revealed in this study. Second, given that women's psychological health is more adversely affected by housing insecurity compared with men, persistent or exacerbating housing insecurity in Korea's housing market may increase the psychological health disparity not only between upper- and lower income groups but also between men and women. Therefore, social services helping vulnerable families in the housing sector should consider not only household-based interventions but also person-centered measures in light of the gender differences in psychological health risks of housing problems. In this regard, intersectoral collaboration among social work, public health, subsidized housing agencies, and governments seems vital to help people with multiple housing problems, particularly women and those with an initial psychological health problem.[35] Such efforts can contribute to reducing gender disparity in health outcomes.

Author statements

Ethical approval

The authors did not need informed consent from participants because the data set is publicly available from the official website (https://www.koweps.re.kr). The Institutional Review Board of the Korea Institute for Health and Social Affairs approved the data set.

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Original Research

Patterns of tobacco or nicotine-based product use and their quitting behaviour among adults in India: a latent class analysis

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ABSTRACT

Objectives: The aims of the study were to identify latent classes of adult tobacco or nicotine-based product users in India, compare their sociodemographic distribution and quitting behaviour and explore the association of quitting behaviour and time to first tobacco use with class membership.
Study design: This was a nationally representative cross-sectional survey.
Methods: Data from the Global Adult Tobacco Survey 2016–2017 in India, which covered adults aged >15 years, were analysed. Latent class analysis was used to examine patterns of tobacco or nicotine-based product use (cigarette, bidi, cigar, e-cigarette, chewable tobacco and snuff) among current tobacco users. Classes were compared across sociodemographic and tobacco use–related characteristics. Various model fit statistics (Akaike, Bayesian and Sample Size–Adjusted Bayesian Information Criteria, Likelihood Ratio Tests and Entropy) and meaningfulness of the classes were used to select the number of latent classes.
Results: Of 21,857 current tobacco users, five latent classes were extracted: 'poly-tobacco use' (103, 0.5%), 'oral chewable products predominantly' (11,306, 51.7%), 'bidi predominantly' (4965, 22.7%), 'cigarette predominantly' (5318, 24.3%) and 'snuff and chewable products' (165, 0.8%). Significant differences between classes emerged on sociodemographics (age, sex, residence, education, wealth quintile, region). 'Bidi predominantly' class was associated with higher likelihood of quit attempts. Compared with 'cigarette predominantly' class, other classes were significantly associated with time to first tobacco use.
Conclusion: We found that people in India could be grouped into five classes based on their tobacco or nicotine-based product use pattern. It may be efficient to tailor messages to different latent classes and address the distinct profiles of these groups of tobacco product users.

Introduction

The adverse health effects of tobacco are well documented in literature.[1,2] Smoking tobacco use alone claimed nearly 7.7 million deaths in 2019 and was the leading risk factor for death among males (20%).[3] Mirroring the global picture, tobacco use is also one of the major causes of death and disease in India, taking 1.35 million lives every year.[4] India is also the second largest consumer and producer of tobacco.[4] A variety of tobacco products are available at very low prices in the country. Nearly 267 million adults (aged ≥15 years) in India (29% of all adults) are users of tobacco according to the Global Adult Tobacco Survey India, 2016–2017.[5] The problem of tobacco use in India is compounded by the fact that people use a variety of smoking and smokeless tobacco products. Smokeless products include a variety of oral chewable products such as betel leaf/paan, khaini, gutkha, gudakhu and pan masala and inhalational products such as snuff. Besides smokeless tobacco products, the use of newer smoking nicotine products such as e-cigarettes and hookah among youths and young adults is on the rise.[6]

To tackle this menace, India passed a comprehensive tobacco control law – the Cigarettes and Other Tobacco Products Act, 2003 to prohibit (1) smoking in public places, (2) direct and indirect advertisements of tobacco products, (3) sale of tobacco products to minors and within 100 yards of any educational institutions and (4) sale without specified graphic health warning labels.[7] However, the implementation of this antitobacco law has been suboptimal and varied across Indian states due to differences in political and administrative structures, organisational and individual capacities, political commitment and the economy of tobacco production and consumption.[8,9]

In India, there is an availability of a wide variety of tobacco products in the market. The use of multiple tobacco products (polytobacco use) in various combinations is high in India. One

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potential explanation for this are the shared underlying factors (e.g. sociodemographic, environmental, behavioural etc.) that may influence the use of multiple types of tobacco products. Previous studies from India have explored the prevalence and correlates of the use of various tobacco products as a binary variable (user/no user).[10–13] Exploring the patterns of polytobacco users will inform the formulation of tailored interventions for specific groups of polytobacco users.

Latent class analysis (LCA) is a statistical method used to reduce the dimensionality of data on heterogeneous factors (e.g. frequency of usage for various tobacco products) by clustering respondents into probabilistic subgroups with different combinations of tobacco use patterns (single or multiple products) rather than a binary variable (user/no user) for individual tobacco products. These unobserved subgroups are called latent classes.[14]

Against this background, we conducted this study among a nationally representative sample of adult tobacco users (aged ≥15 years) in India with the following objectives:

1. To identify distinct classes of tobacco or nicotine-based product users using LCA;
2. To describe the distribution of sociodemographic characteristics, quit intention and attempts in the past 12 months, time to first tobacco use and knowledge about ill effects of tobacco across the latent classes; and
3. To explore the association between quitting behaviour and time to first tobacco use with latent class membership after adjusting for potential confounders.

Methods

Data source

We used nationally representative data of GATS-II (2016–2017) conducted among adults ≥aged 15 years in India. It uses a global standardised methodology to collect information regarding the respondents' sociodemographic characteristics and household information, tobacco use (smoking and smokeless) patterns, cessation, second-hand smoke exposure, economics, media, knowledge, attitudes and risk perceptions of tobacco use. GATS-II was carried out in all the 30 states of India and in the two Union Territories of Chandigarh and Puducherry. The data collection was carried out during August 2016 to February 2017. A multistage, geographically clustered sample design was used to produce data representative of each state and Union Territory. One individual was randomly chosen from each selected household to participate in the survey. The survey included 74,037 participants with household and individual-level response rates at 96.7% and 96%, respectively, thus an overall response rate of 92.9%.[5]

Data collection and management

Field data collection team comprising of two male and two female interviewers, and one supervisor collected data electronically using hand-held devices in the form of tablets. Trained interviewers administered the survey questionnaire in the country's local language(s). The device had the questionnaire in 19 languages, and the interviewer could switch to any of those languages for the interviews. The questionnaire had inbuilt checks, skip patterns and allowable ranges to avoid data errors. At the end of each day, data files from each tablet were transmitted to the cloud server using wireless Internet. These data files were then securely collated from cloud server to a workstation by the data management team. Data quality checks were performed, including data validation and skip patterns, interview time and duration and inspection for any unusual pattern or outliers. In case of any discrepancy, these were reported back to the respective teams and field coordinators. Validated data were then aggregated to generate the master data file for analysis.

Study variables and measurement

The current tobacco user subset was extracted from the GATS data set for performing LCA. This subset of data was obtained from the responses to the following two questions:

"*Do you currently smoke tobacco on a daily basis, less than daily, or not at all?" and*

"*Do you currently use smokeless tobacco on a daily basis, less than daily, or not at all?"*

If the answer to any of the above two questions is daily or less than daily, he/she was considered to be a current tobacco user.

Use of tobacco products

The GATS collected information on the use of various smoking (cigarettes, bidi, cigars/cheroots/cherillos, e-cigarettes, hookah) and smokeless products (betel quid and tobacco, khaini, gutkha, gudakhu, pan masala and snuff), including nicotine-based products such as e-cigarettes and hookah. The category 'Oral chewable tobacco products' was derived by combining betel quid and tobacco, khaini or tobacco lime mixture, gutkha, gudakhu and pan masala.

Cigarette use was assessed by the following questions, 'On average, how many manufactured cigarettes do you currently smoke each day? Also, let me know if you smoke the product, but not every day?' with an open-ended response. For those who do not use product the everyday, the next question was, 'On average, how many manufactured cigarettes do you currently smoke each week?' We recoded responses from the two above-mentioned questions into a dichotomised variable. The respondent was considered to be using cigarette (coded as 1) if the answer to any of the above two questions is >0. The use of other tobacco products was also assessed in a similar manner.

Sociodemographic variables

The following sociodemographic variables were collected as part of the household survey: age in years (categorised into four categories, namely, 15–24 years, 25–44 years, 45–64 years and ≥65 years), gender (male, female), residence (urban, rural), region (north, central, east, north-east, west, south), wealth quintiles, educational status (no schooling, up to primary, up to secondary, higher secondary and above), marital status (single, married, divorced/separated/widowed) and occupation (government or private sector employee, daily wage labourer, self-employed, student, homemaker, retired/unemployed). Six regions of India are defined in the survey as follows: North (Jammu and Kashmir, Punjab, Himachal Pradesh, Chandigarh, Uttarakhand, Haryana, Delhi), Central (Rajasthan, Uttar Pradesh, Chhattisgarh, Madhya Pradesh), East (West Bengal, Jharkhand, Odisha, Bihar), North East (Sikkim, Arunachal Pradesh, Meghalaya, Mizoram, Manipur, Nagaland, Assam, Tripura), West (Gujarat, Maharashtra, Goa) and South (Andhra Pradesh, Telangana, Tamil Nadu, Karnataka, Kerala, Puducherry).

Wealth quintile was calculated from ownership of 14 household items, namely, electricity, flush toilet, fixed telephone, mobile phone, television, radio, refrigerator, car, motorcycle/scooter, washing machine, computer/laptop, Internet connection, air conditioner and electric fan. Weights were calculated by taking the inverse of the proportion of households owning the item.[15] This is based on the assumption that assets owned by a smaller proportion of households are indicative of higher household wealth and are therefore assigned a higher weight. These weights were then used to calculate a total weighted wealth score for each household, which was then divided into five quintiles.

Variables related to tobacco use and quit behaviour

Quit intention was assessed by the following question, 'Which of the following best describes your thinking about quitting smoking/smokeless tobacco?' The options were as follows: quit within the next month, thinking within the next 12 months, quit someday, not interested in quitting, and do not know/refused. Respondents who replied that they want to 'quit within the next month' or 'thinking within the next 12 months' were considered as having quit intention.[16,17]

Quit attempt was assessed by the following question, 'During the past 12 months, have you tried to stop smoking/using smokeless tobacco' (Yes/No).

Quitting behaviour is referred to quit intention or quit attempt in this article.

Time to first tobacco use is defined as consumption of tobacco product within 30 min of waking up from bed. This is assessed by the following question, 'How soon after you wake up do you usually have your first smoke/smokeless tobacco?' The options were as follows: within 5 min, 6–30 min, 31–60 min or more than 60 min. These categories were clubbed to form two categories: ≤30 min and more than 30 min.[18,19]

Knowledge about the ill effects of tobacco was assessed by the following question, 'Based on what you know or believe, does smoking/smokeless tobacco cause serious illness?' (Yes/No).

Data analysis

LCA was used to explore unique patterns of tobacco or nicotine-based product use among the current tobacco users by identifying groups of individuals that share a similar response profile to categorical measured variables. Similar to factor analysis, LCA assumes that the covariation among directly measured categorical variables is explained by a latent factor.[14]

We began by specifying two latent classes and increased the number of classes to seven and then evaluated all the models to find the best fit model. The following six fit statistics were used to compare models: Akaike Information Criteria (AIC), Bayesian Information Criteria (BIC), Sample Size–Adjusted Bayesian Information Criteria (SSA-BIC), Bootstrapped Likelihood Ratio Test (BLRT), Lo-Mendell-Rubin Likelihood Ratio Test (LMRT) and Entropy.[20,21]

The following criteria were used to select the appropriate model:

1. Lower values of AIC, BIC, and SSA-BIC,
2. Higher values of entropy,
3. LMRT and BLRT should be significant ($P < 0.05$),
4. Most importantly, we considered the interpretation and meaningfulness of the classes while selecting the best latent structure.

LCA was performed using MPlus version 8.4, and the output was saved in. sav format, which was later imported into SPSS version 20.0 for cross-tabulations and regression analysis. The MPlus output had additional variables denoting the class membership of each respondent and class membership probabilities.

After identifying the best fit model, the class membership variable was then used as a dependent variable, and a series of cross-tabulations (using Chi-squared tests) were done to examine the distribution of sociodemographic characteristics, tobacco use, quitting behaviour and knowledge about ill effects of tobacco by classes. Multivariable logistic regression analyses were performed to establish the association between quit intention, quit attempt and time to first tobacco use (dependent variables) with the latent classes (independent variable) after adjusting for potential confounders.

Ethics approval

We analysed data from a nationally representative survey, that is, GATS conducted by the Government of India. The data set is available in the public domain for academic/research purpose at the following link: https://www.cdc.gov/tobacco/global/gtss/gtssdata/index.html. The Institute Ethics Committee, All India Institute of Medical Sciences, Nagpur, waived off the need for ethics review for this study.

Results

Sociodemographic characteristics of the study sample

The GATS 2016–2017 covered 74,037 respondents aged ≥15 years; more than half were females (40,265, 54.4%) with a mean age of 39.5 years (SD = 15). Most survey respondents lived in rural locations (47,549, 64.2%) and were married (56,984, 77%), and about one-quarter did not go to any school (18,473, 25%). Nearly one-third of the respondents were homemakers (25,833, 35%), followed by self-employed (13,955, 18.9%) and daily wage labourers (13,749, 18.6%). Of them, 21,857 (29.5%) currently use tobacco in any form. Most current tobacco users were males (15,576, 71.3%) and currently married (18,233, 83.4%), three-quarters were residing in rural locations (16,382, 75%), and nearly one-third had no schooling (6,879, 32%), with a mean age of 43 years (SD = 15). One-third of them were daily wage labourers (6966, 31.9%), followed by self-employed (6406, 29.3%) and homemaker (3,619, 16.6%). In our sample of current tobacco users (n = 21,857), 23.2% were bidi users, 57.1% used chewable tobacco products, 13.5% used cigarettes, 0.8% used cigars, 0.8% used snuff, 0.7% were hookah users and 0.1% used e-cigarettes.

Selection of model

Table 1 presents the model fit statistics for seven models, starting from one class to seven classes. Model with five classes had the lowest BIC value, whereas the 6-class model had the lowest AIC and SSA-BIC. Both the models had high values for entropy (>0.9) indicating good fit; however, the 6-class model included a latent class of users, which was not meaningful in its composition and consisted of 0.03% of the sample. After all these considerations, the 5-class model was selected due to lowest BIC value, adequate entropy (0.915) and meaningfulness of the classes. Table 2 presents the estimated item probabilities for the five identified latent classes. These are the probabilities of being a tobacco product user, given the membership in a latent class. The item probability of 1.000 for chewable products in latent class 2 means that the

probability of being a chewable product user is 100% given the membership in class 2. Table 3 shows the Average Latent Class probabilities for most likely Latent Class Membership (row) by Latent Class (column), which was used to look at classification quality. The diagonal values are closer to one, indicating good class separation.

Latent class description

Five distinct classes were extracted after performing LCA. We labelled the latent classes as 'Poly-tobacco use' (n = 103, 0.5%), 'oral chewable products predominantly' (n = 11,306, 51.7%), 'bidi predominantly (n = 4965, 22.7%), 'cigarette predominantly' (n = 5318, 24.3%) and 'snuff and chewable products' (n = 165, 0.8%). The largest class was the 'oral chewable products predominantly,' covering nearly 52% of the sample.

Comparison of classes on demographics and other tobacco use correlates

There were significant differences in the distribution of sociodemographic and other variables related to tobacco/nicotine product use and quitting behaviour across the identified classes (Table 4).

Compared with other classes who had a male preponderance, the 'oral chewable products predominantly' and the 'snuff and chewable products' classes had a higher proportion of females (39.4% and 72.7%, respectively). A higher percentage of people from the North-East region was observed in 'Poly-tobacco use', 'oral chewable products predominantly' and 'cigarette predominantly' classes, whereas 'bidi predominantly' class had more people from the North, followed by Central and North East.

Nearly one-fifth of the tobacco users in the 'bidi predominantly' and 'cigarette predominantly' classes had the intention to quit tobacco within the next 12 months. In the 'Poly-tobacco use' class, this proportion was low (13.6%). The use of tobacco within 30 min of getting awake was highest in the 'bidi predominantly' class (64.6%) and lowest in the 'cigarette predominantly' class (22.5%). Except for the 'cigarette predominantly' class, all other classes had more than 60% of people from the lowest two wealth quintiles. A similar distribution was also seen in terms of educational status. All latent classes had more than 60% of people educated up to primary school, except for the 'cigarette only,' where >50% of the respondents were educated up to secondary school or higher. Homemakers were one of the predominant group in the 'snuff and chewable products' followed by 'oral chewable products predominantly' class. Among the 'bidi predominantly' class, nearly 40% were daily wage labourers followed by self-employed (33.2%). In the 'oral chewable products predominantly' class also, daily wage labourers were predominant (31.7%), followed by the self-employed (27.4%; Table 4).

Table 1
Model Fit statistics for multiple latent classes of tobacco use pattern.

Latent classes	AIC	BIC	SSA-BIC	Entropy	LMRT	BLRT
1	79,866	79,916	79,891	–	–	–
2	73,471	73,575	73,533	0.766	<0.001	<0.001
3	73,001	73,160	73,097	0.831	<0.001	<0.001
4	72,874	73,090	73,004	0.890	<0.001	<0.001
5	72,803	73,078	72,968	0.915	<0.001	<0.001
6	72,757	73,084	72,954	0.950	0.008	0.04
7	72,772	73,156	73,003	0.786	0.87	1.00

AIC, Akaike Information Criteria; BIC, Bayesian Information Criteria; BLRT, Bootstrapped Likelihood Ratio Test; LMRT, Likelihood Ratio Test; SSA-BIC, Sample Size–Adjusted Bayesian Information Criteria.

Table 2
Item probabilities given the Latent class membership for the 5-class model.

Tobacco product	LC 1	LC 2	LC 3	LC 4	LC 5
Bidi	1.000	0.000	1.000	0.000	0.039
Cigar	0.181	0.001	0.000	0.012	0.000
E-cigarette	0.069	0.001	0.038	0.083	0.000
Hookah	0.081	0.003	0.067	0.044	0.003
Chewable products	0.489	1.000	0.182	0.098	0.466
Snuff	0.022	0.000	0.000	0.000	1.000
Cigarettes	0.528	0.021	0.116	0.630	0.000

LC, latent class.

Table 3
Average latent class probabilities for most likely latent class membership (row) by latent class (column).

Number of classes	Class 1	Class 2	Class 3	Class 4	Class 5
Class 1	0.977	0.000	0.023	0.000	0.000
Class 2	0.000	0.952	0.000	0.048	0.000
Class 3	0.078	0.000	0.923	0.003	0.000
Class 4	0.000	0.001	0.000	0.999	0.000
Class 5	0.023	0.000	0.000	0.000	0.977

Diagonal values are important; optimal if diagonal values are closer to 1.

Association between quitting behaviour and latent class membership

After adjusting for potential confounders, latent class membership was not associated with quit intention. 'Bidi predominantly' class membership was significantly associated with quit attempts (1.5, 1.1–2.2). Compared with 'cigarette predominantly' class, 'bidi predominantly' class membership (5.3, 4.8–5.8) followed by 'Poly-tobacco use' (4.0, 2.7–6.0) and 'oral chewable products predominantly' class (3.8, 3.5–4.1) was strongly associated with time to first tobacco use (Table 5).

Implications

1. Tobacco users could be grouped into five latent classes based on their tobacco or nicotine-based product use with distinct sociodemographic and tobacco use profiles.
2. 'Oral chewable products predominantly' was the largest class with relatively poor quitting behaviour. This implies that besides smokers, we have to direct our cessation efforts towards smokeless tobacco users.
3. Female homemakers should be prioritised as they constitute a substantial proportion of the smokeless tobacco users and are often neglected in our cessation efforts.
4. High nicotine dependency among bidi, polytobacco and smokeless tobacco users is concerning and requires reformulating cessation strategies for these groups.

Discussion

This is the first ever study from India using LCA to explore various patterns of current tobacco/nicotine-based product users and the association of these classes with quitting behaviour and time to first tobacco use. The study had some key findings. First, five distinct latent classes of tobacco/nicotine-based product users were

Table 4
Association of sociodemographic and tobacco use correlates with latent classes of tobacco use among current tobacco users, Global Adult Tobacco Survey 2016–2017, India.

Characteristics	Total (N = 21,857)	Polytobacco use	Oral chewable products predominantly	Bidi predominantly	Cigarette predominantly	Snuff and chewable products	*P*-value
Gender							<0.001
Male	15,576	93 (90.3)	6849 (60.6)	4560 (91.8)	4029 (75.8)	45 (27.3)	
Female	6281	10 (9.7)	4457 (39.4)	405 (8.2)	1289 (24.2)	120 (72.7)	
Residence							<0.001
Urban	5475	20 (19.4)	2653 (23.5)	986 (19.9)	1780 (33.5)	36 (21.8)	
Rural	16,382	83 (80.6)	8653 (76.5)	3979 (80.1)	3538 (66.5)	129 (78.2)	
Region							<0.001
North	2818	08 (7.8)	593 (5.2)	1353 (27.3)	851 (16.0)	13 (7.9)	
Central	4136	15 (14.6)	2533 (22.4)	1027 (20.7)	542 (10.2)	19 (11.5)	
East	3652	10 (9.7)	2524 (22.3)	658 (13.3)	451 (8.5)	09 (5.5)	
North East	6913	53 (51.5)	3511 (31.1)	1017 (20.5)	2305 (43.3)	27 (16.4)	
West	1763	06 (5.8)	1146 (10.1)	261 (5.3)	297 (5.6)	53 (32.1)	
South	2575	11 (10.7)	999 (8.8)	649 (13.1)	872 (16.4)	44 (26.7)	
Marital status							<0.001
Single	2003	14 (13.6)	863 (7.6)	245 (4.9)	872 (16.4)	09 (5.5)	
Married	18,233	84 (81.6)	9428 (83.4)	4446 (89.5)	4153 (78.1)	122 (73.9)	
Divorced/separated/widowed	1621	05 (4.9)	1015 (9.0)	274 (5.5)	293 (5.5)	34 (20.6)	
Educational status (N = 21,844)							<0.001
No schooling	6879	27 (26.2)	3836 (33.9)	1779 (35.8)	1138 (21.4)	99 (60.0)	
Up to primary	6497	44 (42.7)	3371 (29.8)	1672 (33.7)	1380 (26.0)	30 (18.2)	
Up to secondary	6037	26 (25.2)	2996 (26.5)	1215 (24.5)	1772 (33.3)	28 (17.0)	
Higher education	2431	06 (5.8)	1096 (9.7)	297 (6.0)	1024 (19.3)	08 (4.8)	
Wealth quintile							<0.001
First quintile	6715	40 (38.8)	3945 (34.9)	1566 (31.5)	1107 (20.8)	57 (34.5)	
Second quintile	6137	26 (25.2)	3193 (28.2)	1618 (32.6)	1255 (23.6)	45 (27.3)	
Third quintile	3242	11 (10.7)	1694 (15.0)	739 (14.9)	774 (14.6)	24 (14.5)	
Fourth quintile	3598	16 (15.5)	1623 (14.4)	742 (14.9)	1196 (22.5)	21 (12.7)	
Fifth quintile	2165	10 (9.7)	851 (7.5)	300 (6.0)	986 (18.5)	18 (10.9)	
Age category							<0.001
15–24 years	1848	07 (6.8)	891 (7.9)	197 (4.0)	745 (14.0)	08 (4.8)	
25–44 years	10,837	58 (56.3)	5817 (51.5)	2177 (43.8)	2734 (51.4)	51 (30.9)	
45–64 years	6949	31 (30.1)	3474 (30.7)	1981 (39.9)	1396 (26.3)	67 (40.6)	
≥65 years	2223	07 (6.8)	1124 (9.9)	610 (12.3)	443 (8.3)	39 (23.6)	
Occupational status (N = 21,852)							<0.001
Employee (government/private)	2700	07 (6.8)	1245 (11.0)	518 (10.4)	925 (17.4)	05 (3.0)	
Daily wage labourer	6966	31 (30.1)	3582 (31.7)	1986 (40.0)	1327 (25.0)	40 (24.2)	
Self-employed	6406	50 (48.5)	3097 (27.4)	1650 (33.2)	1571 (29.6)	38 (23.0)	
Student	422	02 (1.9)	130 (1.2)	16 (0.3)	274 (5.2)	0 (0.0)	
Homemaker	3619	06 (5.8)	2476 (21.9)	322 (6.5)	751 (14.1)	64 (38.8)	
Retired/unemployed	1739	07 (6.8)	774 (6.8)	472 (9.5)	468 (8.8)	18 (10.9)	
Quit intention within the next 12 months							<0.001
No	17,950	89 (86.4)	9450 (83.6)	3952 (79.6)	4320 (81.2)	139 (84.2)	
Yes	3907	14 (13.6)	1856 (16.4)	1013 (20.4)	998 (18.8)	26 (15.8)	
Morning use of tobacco (<30 min of awakening)							<0.001
No	11,219	45 (43.7)	5221 (46.2)	1759 (35.4)	4119 (77.5)	75 (45.5)	
Yes	10,638	58 (56.3)	6085 (53.8)	3206 (64.6)	1199 (22.5)	90 (54.5)	
Tried to quit tobacco in the last 12 months							<0.001
No	14,774	69 (67.0)	7930 (70.1)	3133 (63.1)	3517 (66.1)	125 (75.8)	
Yes	7083	34 (33.0)	3376 (29.9)	1832 (36.9)	1801 (33.9)	40 (24.2)	
Health care provider visit in the last 12 months							<0.001
No	12,598	71 (68.9)	6586 (58.3)	2659 (53.6)	3196 (60.1)	86 (52.1)	
Yes	9259	32 (31.1)	4720 (41.7)	2306 (46.4)	2122 (39.9)	79 (47.9)	
Knowledge about tobacco							0.008
No	757	4 (3.9)	401 (3.5)	166 (3.3)	172 (3.2)	14 (8.5)	
Yes	21,100	99 (96.1)	10,905 (96.5)	4799 (96.7)	5146 (96.8)	151 (91.5)	

LC Latent Class.

identified, 'oral chewable products predominantly' class being the predominant. Three classes were dominated by the primary use of one product (oral chewable products, cigarettes and bidis), and two classes had use of two or more tobacco products. Second, significant differences between classes emerged on sociodemographic and other variables related to tobacco use and quitting behaviour. Third, 'Bidi predominantly' class membership was associated with quit attempts, and, fourth, compared with 'cigarette predominantly' class, all other latent classes were significantly associated with time to first tobacco use.

Amidst the declining prevalence of single tobacco use, the increased diversity and growing market of alternative tobacco products have led to the rise in the prevalence of dual and polytobacco use in recent years.[22] A recent systematic review found the highest prevalence of polytobacco in the South East Asian (SEA) and European countries. Dual use of smoking and smokeless tobacco

Table 5
Association between quit intention, quit attempt and time to first tobacco use and latent class membership after adjusting for confounders.

Characteristics	Quit intention in the last 12 months	Quit attempt in the last 12 months	Time to first tobacco use <30 min
	OR (95% CI)	OR (95% CI)	OR (95% CI)
Gender			
Male	1.0 (0.9–1.1)	1.1 (1.0–1.2)*	1.3 (1.2–1.4)**
Female	1.0	1.0	1.0
Residence			
Urban	1.0 (0.9–1.1)	1.2 (1.1–1.3)**	1.1 (1.0–1.2)*
Rural	1.0	1.0	1.0
Region			
North	1.0 (0.9–1.2)	0.7 (0.6–0.8)**	1.0 (0.9–1.1)
Central	1.3 (1.1–1.5)**	0.8 (0.7–0.9)**	0.8 (0.7–0.9)*
East	0.9 (0.8–1.1)	0.6 (0.5–0.7)**	1.1 (1.0–1.2)
North East	0.6 (0.5–0.7)**	0.5 (0.5–0.6)**	0.9 (0.8–1.0)
West	1.2 (1.0–1.4)*	0.4 (0.4–0.5)**	1.4 (1.2–1.6)**
South	1.0	1.0	1.0
Marital status			
Single	0.9 (0.7–1.2)	0.9 (0.7–1.1)	0.7 (0.6–0.8)**
Married	1.1 (0.9–1.3)	1.1 (0.9–1.2)	1.0 (0.9–1.1)
Divorced/separated/widowed	1.0	1.0	1.0
Educational status (N = 21,844)			
No schooling	0.7 (0.6–0.8)**	0.7 (0.6–0.8)**	1.7 (1.5–1.9)**
Up to primary	0.9 (0.8–1.0)*	0.9 (0.8–1.0)*	1.4 (1.2–1.5)**
Up to secondary	0.9 (0.8–1.1)	1.0 (0.9–1.1)	1.2 (1.1–1.3)*
Higher education	1.0	1.0	1.0
Wealth quintile			
First quintile	0.9 (0.8–1.0)*	0.8 (0.7–0.9)*	1.0 (0.9–1.2)
Second quintile	1.1 (0.9–1.2)	0.9 (0.8–1.0)*	0.9 (0.8–1.0)
Third quintile	1.1 (0.9–1.2)	1.0 (0.9–1.2)	0.9 (0.8–1.0)
Fourth quintile	0.9 (0.8–1.1)	0.9 (0.8–1.0)*	0.9 (0.8–1.1)
Fifth quintile	1.0	1.0	1.0
Age category			
15–24 years	1.3 (1.1–1.6)*	1.1 (1.0–1.4)*	0.7 (0.6–0.8)**
25–44 years	1.2 (1.1–1.4)*	1.2 (1.1–1.3)*	1.0 (0.9–1.1)
45–64 years	1.2 (1.0–1.3)*	1.1 (1.0–1.2)	1.1 (1.0–1.3)*
≥65 years	1.0	1.0	1.0
Latent class membership			
Polytobacco use	0.9 (0.5–1.9)	1.4 (0.8–2.4)	4.0 (2.7–6.0)**
Oral chewable products predominantly	1.0 (0.7–1.6)	1.2 (0.8–1.7)	3.8 (3.5–4.1)**
Bidi predominantly	1.3 (0.8–2.0)	1.5 (1.1–2.2)*	5.3 (4.8–5.8)**
Cigarette predominantly	1.3 (0.8–1.9)	1.3 (0.9–1.9)	1.0
Snuff and chewable products	1.0	1.0	3.5 (2.5–4.8)**

OR, odds ratio; CI, confidence interval.
Time to first tobacco use is defined as tobacco use within 30 min of getting awake.
*P-value <0.05; **P-value<0.001.

was higher in the SEA countries, the United States of America, and Egypt.[22] In a study among adults from the United States, the largest poly use category was dual use of cigarettes and e-cigarettes.[23] A study in the World Health Organisation SEA Region using Demographic and Health Surveys found highest consumption of dual tobacco (any smoking and smokeless tobacco product) among men in Nepal, followed by India and Bangladesh.[24]

In the SEA countries, predominant smokeless tobacco use along with cigarette/bidi smoking drives dual tobacco product use. Nearly 83% of the global chewing tobacco users live in the south Asia region.[25] These regional differences in polytobacco use pattern are probably due to the availability and/or affordability of alternative tobacco products and different patterns of use of tobacco products. Dual/poly-tobacco or nicotine products use is associated with increased health risks and mortality, greater nicotine dependence and weaker quit intention.[26–29] Therefore, understanding and differentiating the sociodemographic profile and tobacco use behaviours of single/dual/poly-tobacco or nicotine product users is crucial.

We used LCA to explore patterns of tobacco use. The latent classes of tobacco/nicotine product use we identified were less comparable to those found in previous studies. One possible reason for this disagreement is that previous studies using LCA were mostly done in developed countries with predominant use of cigarettes, e-cigarettes and cigars, which drove the composition of the latent classes among all age groups.[30–34] In our setting, the use of oral chewable products and bidis are predominant, which is reflected in the latent classes.

The predominant class was the 'oral chewable products predominantly' covering more than half of the sample most likely because the use of smokeless tobacco products is extremely prevalent and embedded in the culture in South and South-East Asia countries, which accounts for almost 90% of the global smokeless tobacco users.[25,35–37] This class was characterised by a relatively high proportion of female users, rural residents, North-east residents, people belonging to the lower two wealth quintiles, daily wage labourers followed by self-employed and homemakers by occupation and nearly two-thirds educated up to primary level. Previous studies also showed a similar sociodemographic distribution among smokeless tobacco users in India.[10–13] These findings were also echoed in a recent systematic review, which found that rural residents, people in the lowest education category and household wealth group in the low- and middle-income countries were more likely to use smokeless tobacco.[37] The easy accessibility and affordability of smokeless chewable tobacco products could explain this sociodemographic disparity.

The cigarette user class differed from other latent classes in terms of the sociodemographic distribution, with a relatively higher percentage of them being government employees, educated up to secondary level or higher and belonging to the highest two wealth quintiles. Similar socio-economic gradients in cigarette use (as a binary variable yes/no) were also reported by Singh et al. across wealth quintile, occupation and education in an analysis of the previous GATS data set from India.[13] A comprehensive systematic review from low and middle economies also reported higher prevalence of cigarette smoking among men and urban residents, which increased with education and household wealth.[37] Other similar studies from India are not comparable because they have looked at the sociodemographic correlates of smoking, which includes all forms of smoked products, not just cigarettes.[10–12] The higher price of cigarettes compared with other smoked and smokeless products and the perception of cigarette smoking as a status symbol could largely explain the profile of the cigarette user class.[38,39]

This study found poor quitting behaviour (quit intention and attempt) among younger age groups, females, rural residents, those with poor education and belonging to poorer wealth quintiles, which finds concurrence in a similar analysis of the GATS data set from India.[40–42] However, no association of quitting behaviour was observed with age groups and wealth quintiles in some studies.[40,42] Sociodemographic profiling helps us target risk groups (for poor quitting) and tailor interventions to encourage quitting and support successful quitting.

In the adjusted analysis, latent class membership was not associated with quit intention or quit attempt within the past 12 months, except for 'bidi predominantly' class, which had a 50% higher odds of making a quit attempt. This stresses the need for aggressive cessation support for bidi users to make these quit attempts successful. Previous studies from India have had contradictory findings on the association of type of tobacco product (smoking vs smokeless tobacco) with quit intention.[42,43] One probable reason for this contradiction could be the varying period used to define quit intention ranging from 30 days to 12 months.

Although no statistical association was seen in the adjusted analysis, the 'oral chewable products predominantly' class along with 'snuff and chewable products' showed poor quitting behaviour (quit intention or quit attempts) in the last 12 months compared with other classes. Kypriotakis et al. also shared similar findings where smokeless tobacco users were less likely to have tried to quit or plan to quit.[31] Kar et al. analysed the correlates of quit intention in the same survey data set and reported higher quit intention among smokers compared with smokeless tobacco users.[42] These two classes with predominant smokeless product use have a relatively higher proportion of females and homemakers by occupation. This highlights our missed opportunities in terms of cessation efforts towards smokeless products, especially among female homemakers. Our cessation efforts have primarily been focused around smoking cessation and have followed a facility-based strategy, thus targeting mostly the male smokers. Schensul et al. found that social and family influence including husband's tobacco use, positive beliefs and norms about use, poor media exposure and fewer incentives for quitting make it difficult for women to quit without support from the cessation programme.[44] We must, therefore, re-orient our focus to include female homemakers using chewable products in our cessation plans through contextual or family-based strategies.

Our study found the bidi user class to be the most dependent followed by the polytobacco users and smokeless user class, with the cigarette user class reporting the lowest dependency in terms of the proportion of users taking tobacco within 30 min of getting awake from bed. This contradicts previous studies, which found cigarette user class to be the most dependent.[31,45] One possible reason for high nicotine dependency among bidi users could be higher concentration of nicotine in bidis compared with cigarettes, which was demonstrated by a study by Malson et al. in India.[46] Also, there are significant sociodemographic differences between the bidi and cigarette classes, which could have a bearing on the addiction behaviour. The discrepancies in studies could also be attributed to the variation in the prevalent forms of tobacco products in different settings and the varied operational definitions of tobacco dependency used. High nicotine dependency was also observed among smokeless user class compared with smokers in congruent with previous studies from India.[47–49] This could be due to lower harm perceptions, lack of regulation of its use in public places, early age of initiation, poor socio-economic profile and lower educational status among the smokeless user class.[47,49]

High dependency has been consistently observed among polytobacco users compared with single product users similar to the findings of this study.[23,50–52] This could be due to higher addiction potential, lower harm perception and higher nicotine consumption among the polytobacco users than single product users.[52,53] It is also proposed that poly users may be considerably different in their tobacco use motivations compared with other users.[53]

Strengths and limitations

There were some strengths in this study. First, there is lack of literature in low- and middle-income country settings using LCA to explore classes of tobacco users and their sociodemographic and tobacco use correlates. The use of the LCA method allows classification of participants into hidden clusters of tobacco use (single or multiple products) as opposed to a binary user/no user classification for individual tobacco products. Second, the study analysed data from a large nationally representative household survey, with globally standardised methodology and study tools, thereby lending generalizability to the study findings with key national policy implications. Third, the survey comprehensively covered the use of various tobacco products including different forms of smoking and smokeless tobacco.

There were four key limitations in this study. First, the responses to the survey questions were self-reported, and there was no objective way of verifying the responses. This means that social desirability bias cannot be ruled out. Second, the cross-sectional survey design does not allow us to make causal inferences. Third, we also cannot demonstrate the transition between classes over time as we do not have longitudinal data. Future research should prospectively examine a large cohort of tobacco users to understand this complex behaviour over a period of time. Fourth, time to first tobacco use as a proxy for tobacco dependence could be biased. The relationship between these two items depends on the type of product used and has been found to be weak among non-cigarette tobacco user groups.[45]

Policy implications

The study findings have few key policy implications for tobacco use prevention. LCA models that explore unobserved heterogeneity are particularly useful for identifying subgroups for message tailoring. This study provides clear evidence that tobacco prevention efforts cannot just focus on cigarettes or smoked products only. 'Oral chewable products predominantly' class was the largest class with more than 50% of the population. This class also had poor quitting behaviour. This implies that besides smokers, we have to direct our cessation efforts towards smokeless tobacco users. Female homemakers should be prioritised as they constitute a substantial proportion of the smokeless tobacco users and are often

neglected too in our cessation efforts. High nicotine dependency (in terms of time to first tobacco use) among bidi, polytobacco and smokeless tobacco users is also a matter of concern and requires reformulating cessation strategies for these tobacco products.

Conclusion

We have identified five latent classes of users with distinct patterns of tobacco/nicotine-based product use that have different sociodemographic distribution, quitting behaviour and tobacco dependency. As interventions are becoming tailored, classifying people by patterns of use provides a way to create specific interventions for each class. We need to tailor our cessation programme to tackle smokeless tobacco users especially female homemakers and bidi users.

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Competing interests

The authors declare that there are no competing interests.

Data availability

Data are available in public domain from the Global Tobacco Surveillance System Data (GTSS Data) maintained by the Centers for Disease Control and Prevention and freely available to all researchers. Data can be accessed at https://nccd.cdc.gov/GTSSDataSurveyResources/Ancillary/DataReports.aspx?CAID=2.

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Original Research

Perceived health status and satisfaction with healthcare services of detained male individuals: a survey in Italy

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ABSTRACT

Objectives: This study investigated the perceived health status and satisfaction with prison healthcare services of detained male individuals in Italy.
Study design: A cross-sectional study was performed between March and June 2021.
Methods: Of 800 male detained individuals who were invited to participate in the study, 632 returned the self-administered questionnaire, resulting in a response rate of 79%.
Results: Overall, 72.8% of participants reported that they were moderately or completely satisfied with their health status, and 27.2% stated that they were not at all satisfied. Moreover, 66.2% of participants reported that they had at least one health problem or disease, compared with 34% at the time of incarceration, with 35% reporting multiple health problems/diseases. In total, 10.1% of participants requested healthcare when a health problem occurred, and 12.4% were always satisfied with the healthcare that they received. Significant determinants of dissatisfaction with health status were older age, reported health problems/diseases, suicide attempts, emotional problems and no working activity in prison. Significant determinants of dissatisfaction with healthcare services were younger age, health problems at incarceration, suicide attempts and multiple experiences of incarceration.
Conclusions: This study shows that detained male individuals have multiple and frequently unmet health needs. Some of the reported health problems or diseases were present at the time of incarceration, but these often worsened and/or increased during detention. This study highlights the need to promote evidence-based intervention to strengthen the role of healthcare services provided in prisons.

Introduction

The health of Persons Deprived of Liberty (PDL) is a concern for society as a whole and, as stated by the World Health Organisation, is a critical part of broader public health.[1–4] There is overwhelming evidence that incarcerated individuals frequently come from disadvantaged groups within the general population and, as a consequence, are likely to present a poor health status at the time of incarceration. Moreover, it has been shown that confinement in prison may lead to worsening of physical and mental health, in addition to co-occurring health problems, including communicable and non-communicable diseases, and related risk factors, such as drug abuse, unprotected sexual activity, smoking, poor nutrition and lack of physical activity.[5–10] It has been shown that when PDLs return to the community, they have a high risk of injury, suicide and drug use.[11,12]

Facilitating access to health services during incarceration plays a crucial role in public health. It provides an opportunity to implement healthcare, disease prevention and health promotion programmes to a population group that may not otherwise have access to these services. The World Health Organisation has recommended that prison healthcare services should be independent of prison administration and integrated with services provided to the general population by the public health systems.[3] In Italy, healthcare for detained individuals is provided through the National Health System (NHS) and, according to the Italian Legislation, detained individuals should receive the same healthcare provided to all citizens. The management of healthcare to detained individuals is overseen by Local Health Units that provide specific

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services inside the prisons or, when needed, in hospitals or outpatient services of the NHS located outside the prisons.[13,14]

To date, there is limited evidence on the overall health status and satisfaction with health services of incarcerated individuals. Previous studies have focussed on infectious diseases,[10,15] mental health and drug abuse; [5–8,16,17] however, in most studies, there was no direct involvement of detained individuals providing their point of view on perceived health status and satisfaction with healthcare services. Therefore, this study aims to investigate the health status and access to health services from the perspective of PDL. Moreover, the determinants of perceived health status and satisfaction with healthcare services provided during detention were also explored.

Methods

Study design and sampling

This cross-sectional study was performed between March and June 2021 and was part of a larger project conducted by the University of Campania "Luigi Vanvitelli" and the Joint Operational Unit for "Health Protections and Prison Institutions" to investigate several health-related issues of detained individuals in three prisons in the Campania region of southern Italy.[18,19] Each selected prison hosted individuals awaiting trial and those who had already been convicted, serving both short- and long-term sentences, and included low, medium and high security sections. The details of the study project have been previously described;[18] in brief, a stratified sampling method was used to randomly select the study population. Specifically, after prison directors provided consent for the study to be conducted, detained males aged ≥18 years were stratified by their detention status (i.e. low, medium or high security), and a proportional number of individuals were randomly selected from each group. A sample size of 600 participants was required, assuming a 50% positive perception of health status, a 95% confidence interval (CI), a 5% error and a response rate of 80%. Trained investigators from the research team approached potential participants to provide information about the study, indicating that the questionnaire completion was voluntary and anonymous, and asking if they would like to participate. Written informed consent was obtained from each participant, and no incentives were provided.

Survey instrument

The self-administered questionnaire was completed in prison cells and returned to the research team. Collected data included sociodemographic characteristics, detention details, lifestyle habits prior and during incarceration, perceived physical and mental health status, and related limitations on working, social and regular daily activities. In addition, health needs during detention, specifically in the previous year, access to healthcare services, as well as satisfaction about the healthcare received were investigated. Finally, participation in activities related to healthy lifestyles, as well as to social and working reintegration activities were also assessed. Most questions were closed ended and in various formats (e.g. yes/no, multiple choices, 3 or more point Likert scales).

Pilot study and ethical approval

The data collection tool was pretested on a random sample of 25 individuals, and the necessary amendments were made to the final data collection tool. The study was approved by the Ethics Committee of the Local Health Unit Napoli 1 (protocol code: 297) and of the Local Health Unit of Caserta (protocol code: 400).

Statistical analyses

All analyses were performed using the statistical software Stata version 15.[20] Descriptive statistics and unadjusted testing for association between the independent variables and the outcomes of interest were conducted using Chi-squared test and Student's *t*-test.

All independent variables with a *P*-value ≤0.25 in the univariate analyses and/or considered potential determinants of the selected outcomes were introduced in the multivariate stepwise logistic regression models constructed to identify factors associated with these two outcomes of interest: perceived satisfaction with health status (Model 1) and satisfaction with prison healthcare services (Model 2). Specifically, the first outcome investigating satisfaction with health status (Model 1), which was originally structured in a 3-point Likert scale format, was dichotomised as follows: not at all satisfied = 0; moderately/completely satisfied = 1; and the second outcome investigating satisfaction with prison healthcare services (Model 2), originally structured in a 5-point Likert scale format, was dichotomised as follows: never satisfied = 0; rarely/sometimes/often/always satisfied = 1.

The following independent variables were included in all models: age in years (18–30 = 1; 31–40 = 2; 41–50 = 3; >50 = 4), children (no = 0; yes = 1), education level (primary school = 1; middle school = 2; high school or university degree = 3), having an occupation before detention (no = 0; yes = 1), first detention (no = 0; yes = 1), working activity in prison (no = 0; yes = 1), type of cell (individual = 0; shared = 1), lifetime use of drugs (no = 0; yes = 1), smoking (past/never smoker = 0; current smoker = 1), having participated in preventative activities related to healthy lifestyles (no = 0; yes = 1), having attended any social or working reintegration activities (no = 0; yes = 1), having ever attempted suicide within prison (no = 0; yes = 1), self-reported frequency of emotional problems (never/rarely/sometimes = 0; often/very often = 1), self-reported health problems in the previous year (no = 0; yes = 1) and current health problems/diseases (no = 0; yes = 1). In addition, the variables 'having ever received at least an additional medical examination in prison' (no = 0; yes = 1) and 'self-reporting health problems or diseases at the time of incarceration' (no = 0; yes = 1) were included in Model 1 and Model 2, respectively.

The significance level for inclusion and elimination variables in the multivariate stepwise logistic regression models were *P*-values of 0.2 and 0.4, respectively. The results of the multivariate models have been expressed as odds ratios (ORs) and 95% CIs. Two-tailed tests were conducted, and a *P*-value ≤0.05 was considered statistically significant.

Results

Sociodemographic characteristics, detention details and lifestyle habits of participants

Of 800 detained individuals who were invited to participate in the study, 632 returned the questionnaire, resulting in a response rate of 79%. Table 1 shows the sociodemographic, detention and lifestyle characteristics of the respondents. The mean age was 42.1 years (SD ±12.02, range 18–80 years), the majority (95%) were Italians, one-quarter (27.1%) had obtained a high school or university degree, more than half (61.5%) were married or cohabitant, 77.6% had at least one child, 53.6% were employed before detention, and the large majority (91.1%) lived in shared cells. In total, 28.4% of participants were involved in some working activity, and no significant differences in reported health status ($P = 0.121$) and age ($P = 0.802$) were found with those without a working activity,

Table 1
Sociodemographic characteristics, detention details and lifestyle habits of study participants and the associated perceived satisfaction with health status and healthcare received.

Characteristics	Total		Being moderately or completely satisfied with health status		Being sometimes or always satisfied with healthcare received	
	n	%	n	%	n	%
Sociodemographic characteristics						
Age, years (n = 631)[a]	42.1 ± 12.02 (18–80)[b]					
18–30	124	19.6	107	86.3	83	68
31–40	183	29.0	149	81.9	142	80.7
41–50	164	26.0	105	64	111	73
>50	160	25.4	97	61.4	111	76.5
			$\chi 2 = 35.818$, df = 3, $P < 0.001$		$\chi^2 = 6.708$, df = 3, $P = 0.082$	
Nationality (n = 626)[a]						
Italian	595	95.0	434	73.2	419	75.6
Non-Italian	31	5.0	23	74.2	25	89.3
			$\chi^2 = 0.015$, df = 1, $P = 0.902$		$\chi^2 = 3.108$, df = 1, $P = 0.078$	
Marital status (n = 621)[a]						
Married/cohabitant	382	61.5	274	71.9	270	75.4
Unmarried/widowed/separated/divorced	239	38.5	175	73.8	170	74.2
			$\chi^2 = 0.272$, df = 1, $P = 0.602$		$\chi^2 = 0.104$, df = 1, $P = 0.747$	
Children (n = 615)[a]						
None	138	22.4	108	78.8	93	70.4
1	106	17.2	79	74.5	84	81.5
2	161	26.2	116	72.5	107	71.3
>2	210	34.2	142	67.9	150	76.9
			$\chi^2 = 5.162$, df = 3, $P = 0.160$		$\chi^2 = 5.240$, df = 3, $P = 0.155$	
Education level (n = 619)[a]						
High school or university degree	168	27.1	127	76	121	76.6
Middle school	354	57.2	262	74.4	255	75.2
Primary school	97	15.7	59	60.8	65	73
			$\chi^2 = 8.372$, df = 2, $P = 0.015$		$\chi^2 = 0.385$, df = 2, $P = 0.825$	
Occupation before detention (n = 623)[a]						
Employed	334	53.6	243	73	248	77.5
Unemployed	289	46.4	208	72.2	194	72.1
			$\chi^2 = 0.044$, df = 1, $P = 0.834$		$\chi^2 = 2.529$, df = 1, $P = 0.133$	
Detention details						
Detention institution (n = 632)						
Prison 1	238	37.7	157	66.5	162	71
Prison 2	200	31.6	146	73.4	147	79.9
Prison 3	194	30.7	155	79.9	139	75.5
			$\chi^2 = 9.662$, df = 2, $P = 0.008$		$\chi^2 = 4.281$, df = 2, $P = 0.118$	
First detention (n = 617)[a]						
Yes	283	45.9	223	79.4	214	79
No	334	54.1	226	67.9	226	72.2
			$\chi^2 = 10.241$, df = 1, $P = 0.001$		$\chi^2 = 3.57$, df = 1, $P = 0.059$	
Length of detention, months (n = 357)[a]	94.3 ± 84.2 (1–480)[b]					
Working activity in prison (n = 567)[a]						
Yes	161	28.4	130	80.7	118	77.1
No	406	71.6	280	69.5	281	73.2
			$\chi^2 = 7.357$, df = 1, $P = 0.007$		$\chi^2 = 0.893$, df = 1, $P = 0.345$	
Type of cell (n = 562)[a]						
Individual	50	8.9	32	65.3	40	81.6
Shared	512	91.1	377	73.8	360	74.5
			$\chi^2 = 1.629$, df = 1, $P = 0.202$		$\chi^2 = 1.202$, df = 1, $P = 0.273$	
Lifestyle habits						
Lifestyle Smoker (n = 627)[a]						
Past/never	189	30.1	131	69.7	133	75.1
Current	438	69.9	324	74.3	311	74.9
			$\chi^2 = 1.427$, df = 1, $P = 0.232$		$\chi^2 = 0.003$, df = 1, $P = 0.959$	
Daily number of cigarettes in current smokers (n = 401)[a]	18.3 ± 9.16 (2–60)[b]					

Table 1 (*continued*)

Characteristics	Total		Being moderately or completely satisfied with health status		Being sometimes or always satisfied with healthcare received	
	n	%	n	%	n	%
Lifetime use of drugs (n = 626)[a]						
Yes	313	50.0	234	75.5	229	75.8
No	313	50.0	221	70.6	217	74.6
			$\chi^2 = 1.881$, df = 1, $P = 0.170$		$\chi^2 = 0.126$, df = 1, $P = 0.723$	
Type of drugs used before detention (n = 310)[a,c,d]						
Cocaine	235	75.8	–	–	–	–
Marijuana/hashish	227	73.2	–	–	–	–
Crack	74	23.9	–	–	–	–
Ecstasy	38	12.3	–	–	–	–
Heroin	51	16.4	–	–	–	–
Barbiturates/tranquilizers	22	7.1	–	–	–	–
Use of drugs during detention (n = 288)[a,c]						
Yes	21	7.3	11	52.4	13	61.9
No	267	92.7	195	73	201	77.6
			$\chi^2 = 4.077$, df = 1, $P = 0.043$		$\chi^2 = 2.658$, df = 1, $P = 0.103$	
Type of drugs used during detention (n = 20)[a,c,d]						
Marijuana/hashish	12	60.0	–	–	–	–
Barbiturates/tranquilizers	6	30.0	–	–	–	–
Cocaine	8	40.0	–	–	–	–
Crack	2	10.0	–	–	–	–

[a] In brackets the number of respondents to each item.
[b] Mean ± standard deviation (range).
[c] Only among those who reported to use drugs.
[d] Multiple responses allowed.

although satisfaction with health status was significantly higher among those who worked (80.7%) compared with those not working (69.5%; $P = 0.007$). For 45.9% of participants, this was their first detention, and the mean time spent in prison was almost 8 years. Just more than two-thirds (69.9%) of participants reported that they were current smokers, 50% admitted having ever used illicit drugs, and 7.3% reported using drugs while in prison.

Self-reported satisfaction with health status and quality of life

Overall, 72.8% of detained male individuals reported being moderately or completely satisfied with their health status, whereas 27.2% were not at all satisfied. There was significantly higher dissatisfaction with health status in older (>40 years) compared with younger (≤40 years) participants (37.3% vs 16.3%; $P < 0.001$). Moreover, 34.7% and 42.6% of PDL reported perceived limitations in performing regular daily activities as a result of physical or emotional health problems, respectively. In addition, 26% and 37.5% of participants had perceived limitations with normal social activities due to their physical or emotional health conditions, respectively (Table 2).

Self-reported health status

At the time of the survey, 66.2% of participants reported to have at least one health problem or disease, compared with 34.3% at the time of incarceration. Older individuals (aged >40 years) reported a significantly higher frequency of health problems/diseases than younger individuals (aged ≤40 years) both currently (76.9% vs 54.9%; $P < 0.001$) and at the time of incarceration (41.7% vs 26.3%; $P < 0.001$). The most frequently reported current health issues were dental health problems (44.7%), arthritis or rheumatic pain (40.4%), cardiovascular diseases (36.5%), emotional problems (30.3%), emphysema and chronic obstructive pulmonary disease (20.4%) and diabetes (13.9%). Significant differences between age cohorts (≤40 and >40 years) were seen for some health problems, including arthritis or rheumatic pain (45.1% vs 33.9%, $P = 0.023$) and cardiovascular diseases (44.3% vs 25%, $P < 0.001$), which were more frequent in older individuals. In contrast, emotional problems were more frequent in younger than older individuals (35.1% vs 27.1%), although this difference was not significant ($P = 0.082$).

In total, 35.1% of participants reported multiple health problems/diseases; specifically, 15.5% declared two, 11.8% three, 4.5% four and 3.3% from five to seven health problems/diseases. Among those with health problems/diseases, a higher number of comorbidities was associated with a lower satisfaction with health status, with the mean number of comorbidities among satisfied and dissatisfied individuals being 1.8 and 2.5, respectively ($P < 0.001$). Among individuals who reported having two health problems/diseases, the most frequent associations were dental health problems and arthritis or rheumatic pain (22.7%), and cardiovascular diseases and arthritis or rheumatic pain (12.4%); likewise, among those who reported the coexistence of three health problems/diseases, the most frequent were dental health problems, arthritis or rheumatic pain and cardiovascular diseases (18.9%), followed by dental health problems, arthritis or rheumatic pain and emotional problems (17.6%).

Half (50.2%) of detained individuals reported to have had at least one health problem in the previous year, with a significantly higher frequency in older (aged >40 years) than younger (aged ≤40 years) individuals (58.2% vs 41.6%; $P < 0.001$), and 57.8% and 50.2% perceiving a healthcare need (e.g. medical examination, prescription of drugs) for a physical or emotional health problem, respectively. In total, 38% of respondents self-reported that they often or very often have emotional problems, with 8.7% stating that they had attempted suicide inside prison and 7.5% outside of prison. Overall, 52.4% of participants believed that their health had worsened or strongly worsened during incarceration (Table 3); this

Table 2
Self-reported health status and quality of life of detained persons (N = 632).

Perceived satisfaction/limitation	n	%
Perceived satisfaction with health status (n = 629)[a]		
Not at all	171	27.2
Moderate	316	50.2
Complete	142	22.6
Perceived satisfaction with quality of life (n = 620)[a]		
Not at all	237	38.2
Moderate	271	43.7
Complete	112	18.1
Perceived limitations of regular daily activities as a result of physical health (n = 619)[a]		
Not at all	404	65.3
Moderate	138	22.3
Complete	77	12.4
Perceived limitations of regular daily activities as a result of emotional problems (depression, anxiety; n = 629)[a]		
Not at all	361	57.4
Moderate	181	28.8
Complete	87	13.8
Perceived limitations with working activities as a result of physical health (n = 624)[a]		
Not at all	415	66.5
Moderate	130	20.8
Complete	79	12.7
Perceived limitations with working activities as a result of emotional problems (depression, anxiety; n = 621)[a]		
Not at all	410	66.0
Moderate	140	22.6
Complete	71	11.4
Perceived limitations with normal social activities as a result of physical health (n = 623)[a]		
Not at all	461	74.0
Moderate	120	19.3
Complete	42	6.7
Perceived limitations with normal social activities as a result of emotional problems (depression, anxiety; n = 624)[a]		
Not at all	390	62.5
Moderate	163	26.1
Complete	71	11.4

[a] In brackets the number of respondents to each item.

perception was higher in older (aged >40 years) than younger (aged ≤40 years) individuals (59.8% vs 44.2%; $P < 0.001$).

Self-reported access and satisfaction with healthcare services and prevention or health promotion activities

In terms of access to healthcare services, 84.8% of participants had received at least one additional medical examination during detention, and 10.1% had been admitted to hospital in the previous year (Table 3). However, when asked about demand for healthcare, only 10.1% of participants reported that in the presence of a health problem, they always request a medical examination. Moreover, among those who have had contact with healthcare services, only 12.4% reported to have always been satisfied with the healthcare received. The three prisons in this study showed similar healthcare services satisfaction ratings, ranging from 10.9% to 14.5%.

Regarding health promotion and disease prevention interventions, only 10.8% of participants participated in prevention activities related to healthy lifestyles that mainly focused on smoking (57.6%), nutrition (47%) and alcohol consumption (42.5%). However, 30.5% of respondents took part in training courses aimed at social or working reintegration activities, and no significant differences were found in the reported health status (current health problems/diseases) between participants and non-participants (70.4% vs 63.9%; $P = 0.121$). Among participants in these courses, 84.5% considered them to be useful.

Univariate and multivariate regression analyses

The results of the univariate analysis investigating the associations of several variables with satisfaction with health status and satisfaction with healthcare services are reported in Tables 1 and 3. Satisfaction with health status was found to be significantly higher in younger individuals (86.3% vs 61.4%; $P < 0.001$), with higher education level (76% vs 60.8%, $P = 0.015$), who perform a working activity in prison (80.7% vs 69.5%; $P = 0.007$), during their first detention (79.4% vs 67.9%; $P = 0.001$), in those without current (90.5% vs 64.4%; $P < 0.001$), previous year (87.5% vs 58.5%; $P < 0.001$) or time of incarceration health problems/diseases (83.1% vs 54.1%; $P < 0.001$), in those who did not perceive their health had worsened during detention (91.2% vs 57.3%; $P < 0.001$), with low frequency of emotional problems (85% vs 53.5%; $P < 0.001$), with no perceived healthcare needs for physical (89% vs 60.9%; $P < 0.001$) or emotional problems (85.4% vs 59.9%; $P < 0.001$), who have not attempted suicide in prison (76.1% vs 41.5%; $P < 0.001$), have not been admitted to hospital in the previous year (75% vs 52.5%; $P < 0.001$) and in those who do not always seek medical examinations in case of health problems (74.9% vs 58.7%; $P = 0.006$). However, in the multivariate analysis, only some of these variables were significantly associated to satisfaction with health status. Specifically, detained individuals aged 41–50 years (OR = 0.37; 95% CI = 0.15–0.88) and >50 years (OR = 0.27; 95% CI = 0.11–0.66) compared with those aged 18–30 years were significantly less likely to be satisfied with their health status, as well as those who reported at least one health problem (OR = 0.35; 95% CI = 0.2–0.62), who attempted suicide in prison (OR = 0.41; 95% CI = 0.19–0.88) and those who often or very often self-reported emotional problems (OR = 0.36; 95% CI = 0.21–0.6). In contrast, individuals who had been involved in a working activity in prison (OR = 1.84; 95% CI = 1.02–3.31) were significantly more likely to be satisfied with their health status (Model 1 in Table 4).

In the univariate analysis for satisfaction with healthcare services provided in prison, it was significantly higher in those who did not perceive their health had worsened during detention (84.4% vs 68%;

Table 3
Self-reported health conditions/diseases and access to healthcare services of detained individuals and the associated perceived satisfaction with health status and health care received (N = 632).

Characteristics	Total		Being moderately or completely satisfied with health status		Being sometimes or always satisfied with healthcare received	
	n	%	n	%	n	%
Self-reported health conditions/diseases						
Current health problems/diseases (n = 620)[a,b]						
No	212	33.8	191	90.5	155	79.5
Yes	415	66.2	266	64.4	291	73.3
			$\chi^2 = 48.590$, df = 1, $P < 0.001$		$\chi^2 = 2.694$, df = 1, $P = 0.101$	
Dental health problems	186	44.7	–	–	–	–
Arthritis or rheumatic pain	168	40.4	–	–	–	–
Cardiovascular diseases	152	36.5	–	–	–	–
Emotional problems (anxiety, depression)	126	30.3	–	–	–	–
Emphysema and COPD	85	20.4	–	–	–	–
Diabetes	58	13.9	–	–	–	–
Gastro-intestinal diseases	22	5.3	–	–	–	–
Kidney and urinary diseases	20	4.8	–	–	–	–
Infectious diseases	12	2.9	–	–	–	–
Neurological diseases	8	1.9	–	–	–	–
Allergic diseases	7	1.7	–	–	–	–
Perceived healthcare needs (medical examination, prescription of drugs, etc.) for physical health problems (n = 623)[a]						
Not at all	263	42.2	234	89	184	75.4
Moderate/complete	360	57.8	218	60.9	256	74.2
			$\chi^2 = 60.351$, df = 1, $P < 0.001$		$\chi^2 = 0.074$, df = 1, $P = 0.785$	
Perceived healthcare needs (medical examination, prescription of drugs, etc.) for emotional problems (n = 620)[a]						
Not at all	309	49.8	264	85.4	224	77.2
Moderate/complete	311	50.2	185	59.9	214	75.5
			$\chi^2 = 50.829$, df = 1, $P < 0.001$		$\chi^2 = 1.716$, df = 1, $P = 0.190$	
Self-reported health problems in the previous year (n = 624)[a]						
No	311	49.8	272	87.5	226	77.4
Yes	313	50.2	182	58.5	218	73.4
			$\chi^2 = 66.056$, df = 1, $P < 0.001$		$\chi^2 = 1.267$, df = 1, $P = 0.260$	
Self-reported health problems/diseases at the time of incarceration (n = 604)[a]						
No	397	65.7	330	83.1	285	75
Yes	207	34.3	111	54.1	153	77.30
			$\chi^2 = 57.941$, df = 1, $P < 0.001$		$\chi^2 = 0.366$, df = 1, $P = 0.545$	
Perception of overall health conditions after incarceration (n = 603)[a]						
Strongly worsened/worsened	316	52.4	180	57.3	204	68
Unchanged/Improved/Strongly improved	287	47.6	262	91.2	232	84.4
			$\chi^2 = 88.902$, df = 1, $P < 0.001$		$\chi^2 = 20.959$, df = 1, $P < 0.001$	
Self-reported frequency of emotional problems (anxiety, depression; n = 603)[a]						
Never/rarely/sometimes	374	62	318	85	280	78.2
Often/very often	229	38	121	53.5	160	61.1
			$\chi^2 = 71.138$, df = 1, $P < 0.001$		$\chi^2 = 3.764$, df = 1, $P = 0.052$	
Having ever attempted suicide within prison (n = 612)[a]						
No	559	91.3	424	76.1	409	76.7
Yes	53	8.7	22	41.5	33	63.4
			$\chi^2 = 29.495$, df = 1, $P < 0.001$		$\chi^2 = 4.519$, df = 1, $P = 0.034$	
Access to healthcare services						
Having ever received at least one medical examination in prison (n = 610)[a]						
No	93	15.2	72	77.4	50	57.5
Yes	517	84.8	371	71.9	387	78.5
			$\chi^2 = 1.211$, df = 1, $P = 0.271$		$\chi^2 = 17.602$, df = 1, $P < 0.001$	
Hospital admission in the previous year (n = 612)[a]						
No	550	89.9	411	75	393	75.6
Yes	62	10.1	32	52.5	42	71.2
			$\chi^2 = 14.065$, df = 1, $P < 0.001$		$\chi^2 = 0.547$, df = 1, $P = 0.460$	

(*continued on next page*)

Table 3 (*continued*)

Characteristics	Total		Being moderately or completely satisfied with health status		Being sometimes or always satisfied with healthcare received	
	n	%	n	%	n	%
Self-reported frequency of medical examination in case of health problems (n = 623)[a]						
Never/rarely/sometimes/often	560	89.9	417	74.9	407	76.9
Always	63	10.1	37	58.7	37	59.7
			$\chi^2 = 7.515$, df = 1, $P = 0.006$		$\chi^2 = 8.848$, df = 1, $P = 0.003$	
Perceived satisfaction						
Perceived satisfaction for healthcare received (n = 596)[a]						
Never	148	24.8	–	–	–	–
Rarely/sometimes/often/always	448	75.2	–	–	–	–
Perceived satisfaction with health status (n = 629)[a]						
Not at all	171	27.2	–	–	106	66.2
Moderate/complete	458	72.8	–	–	341	78.7
					$\chi^2 = 9.841$, df = 1, $P = 0.002$	

COPD, chronic obstructive pulmonary disease.
[a] In brackets the number of respondents to each item.
[b] Multiple responses allowed.

$P < 0.001$), who had not attempted suicide in prison (76.7% vs 63.4%; $P = 0.034$), who had received at least one medical examination (78.5% vs 57.5%; $P < 0.001$), who do not always seek medical examinations in case of health problems (76.9% vs 59.7%; $P = 0.003$) and in those who are satisfied with their health status (78.7% vs 66.2%, $P = 0.002$). The results of the multivariate analysis showed that older detained individuals and those who were in their first detention (OR = 1.71; 95% CI = 1.11–2.64) were significantly more likely to being sometimes or always satisfied by the healthcare received, whereas those who self-reported health problems or diseases at the time of incarceration (OR = 0.35; 95% CI = 0.23–0.55) and those who had attempted suicide in prison (OR = 0.51; 95% CI = 0.27–0.97) were significantly more likely to never be satisfied with the healthcare received (Model 2 in Table 4).

Discussion

The present study provides a detailed assessment of the self-reported health status, satisfaction with health status and access and satisfaction with healthcare services of incarcerated male individuals in an area of Southern Italy.

One of the main issues addressed in the present study was satisfaction with health status. The results show that more than one-quarter of participants were not at all satisfied with their health status, which is less than the 31.6% reported in a similar study conducted several years ago in the same area.[21] However, in the study by Nobile et al.,[21] self-reported health problems/diseases were reported by 81.9% of respondents[21] compared with 66.2% in the current investigation, where the presence of health problems/diseases was found to be associated with lower satisfaction with health status. The present study result is also less than the 47.9% of detained individuals who self-rated their health from very bad to fair in Belgium [22] but substantially higher than the adult male general population in Italy (5.7%).[23] However, as for all health surveys, comparisons among different populations should be made cautiously due to differences in methods, contexts and timings of the investigations.

The analysis of self-reported health problems is concerning because more than two-thirds of participants reported to have at least one health problem or disease, compared with only one-third at the time of incarceration. These results suggest that there may be a deterioration, at least perceived, of health status during detention, which is confirmed by 52.4% of respondents stating that their overall health conditions have worsened or strongly worsened following incarceration. In a matched cohort study conducted by Dirkzwager et al.[24] in the Netherlands, electronic health records of detained individuals were compared with those of non-detained individuals. Health status before detention was found to be inferior in detained individuals, suggesting that individuals from disadvantaged population groups are more likely to enter detention. However, in the study by Dirkzwager et al.,[24] no changes in health problems between pre- and post-detention were observed, illustrating a missed opportunity for healthcare services to address the health needs of detained individuals. Moreover, as previously reported in several investigations of detained populations,[21,25–28] the most frequently mentioned health problems involve dental health and underlying chronic conditions. These findings highlight the epidemiological and demographical changes that are seen in the general population are also occurring in the detained population, including a growing older population in many prisons.[29] Indeed, in a recent systematic review on the health needs of US older PDL, chronic physical conditions and limitations in daily activities were the most frequently reported areas of concern.[30] This finding is in line with the present study results, which showed perceived limitations of social and regular daily activities due to physical or emotional problems. Thus, to provide effective healthcare and health promotion to the detained population, interventions should target lifestyle behaviours that are responsible for chronic conditions, such as smoking, physical activity and diet, and the management of chronic conditions through primary healthcare involving the chronic care model.[31] However, it is alarming, but not surprising, that more than two-thirds of PDL are current smokers. Indeed, a recent systematic review on smoking prevalence in prisons from 50 countries found that smoking by incarcerated individuals exceeded community rates by 1.04- to 62.6-fold and that community tobacco cessation interventions were also effective in the prison setting.[32]

Mental health problems, which were self-reported by 30% of participants, are an area of concern. Self-reported mental health problems are problematic to analyse;[16] thus, systematic reviews have consistently shown high prevalence of mental disorders in detained persons, ranging from 4% for psychotic illness to 48% for drug misuse.[16] It is important to note that as for other health-

Table 4
Multiple logistic regression analysis results examining determinants of perceived satisfaction about health status and health care received.

Variable	OR	95% CI	*P*-value
Model 1. Being moderately or completely satisfied with health status			
Log likelihood=−209.81, χ^2=129.93 (14 df), P < 0.0001, No. of observations=475			
Self-reported frequency of emotional problems (anxiety, depression)			
No (Never/rarely/sometimes)	1.00[a]		
Yes (Often/very often)	0.36	0.21–0.6	<0.001
Self-reported health problems in the previous year			
No	1.00[a]		
Yes	0.35	0.20–0.62	<0.001
Age, years			
18–30	1.00[a]		
31–40	0.68	0.29–1.59	0.373
41–50	0.37	0.15–0.88	0.024
>50	0.27	0.11–0.66	0.004
Having ever attempted suicide within prison			
No	1.00[a]		
Yes	0.41	0.19–0.88	0.023
Working activity in prison			
No	1.00[a]		
Yes	1.84	1.02–3.31	0.043
Having attended any social or working reintegration activities			
No	1.00[a]		
Yes	1.63	0.94–2.84	0.081
First detention			
No	1.00[a]		
Yes	1.49	0.90–2.48	0.120
Education level			
Primary school	1.00[a]		
Middle school	1.7	0.87–3.34	0.120
High school or university degree	1.48	0.71–3.08	0.297
Current health problems/diseases			
No	1.00[a]		
Yes	0.6	0.29–1.24	0.169
Children			
No	1.00[a]		
Yes	0.74	0.38–1.44	0.374
Lifetime use of drugs			
No	1.00[a]		
Yes	0.79	0.46–1.36	0.392
Model 2. Being sometimes or always satisfied by healthcare received			
Log likelihood = −277.6, χ^2 = 44.19 (7 df), P < 0.0001, No. of observations = 542			
Self-reported health problems or diseases at the time of incarceration			
No	1.00[a]		
Yes	0.35	0.23–0.55	<0.001
Age, years			
18–30	1.00[a]		
31–40	2.73	1.51–4.92	0.001
41–50	2.4	1.30–4.45	0.005
>50	2.64	1.42–4.92	0.002
First detention			
No	1.00[a]		
Yes	1.71	1.11–2.64	0.014
Having ever attempted suicide within prison			
No	1.00[a]		
Yes	0.51	0.27–0.97	0.040
Having participated to prevention activities related to healthy lifestyle			
No	1.00[a]		
Yes	0.48	0.97–4.48	0.060

CI, confidence interval; OR, odds ratio.
[a] Reference category.

related problems in prison, it is difficult to determine whether the high prevalence is a consequence of imprisonment or if it was high before detention.[16]

Poor satisfaction with health status in detained individuals was associated with the occurrence of health problems in the previous year, suicide attempts and emotional problems, as well as older age, which deserves careful consideration. Several health-related characteristics were associated with age, with older individuals reporting a significantly higher frequency of current and past health problems/diseases, specifically arthritis and cardiovascular diseases, and a perceived worsening of their health during incarceration. Therefore, the lower satisfaction with health status reported by older individuals may be because of greater deterioration in health conditions in this age group because all the determinants of satisfaction are related to reported physical and emotional health status.

The present study results suggest that satisfaction with health status is a good indicator of mental and physical health conditions. This finding was also reported in a recent study of the general population in Italy. The authors proposed integrating 'satisfaction with health status' within studies investigating general population health needs to help policymakers predict healthcare demand,

assess the subjective effectiveness of the treatment offered by the NHS and identify areas of inequity requiring special attention.[33]

It is interesting that working activity in prison was found to be a determinant of satisfaction with health status despite age, and reported health problems/diseases did not differ between workers and non-workers, suggesting that working activity may produce a sense of well-being in detained individuals. This result is in line with a previous study that showed working activity was a predictor of detained individuals' self-confidence in their ability to protect themselves from COVID-19 infection.[16] In the Italian legislation, working activity is one of the key elements of rehabilitation treatment for detained individuals, aimed at offering concrete opportunities for social reintegration and recovery.[34] In the present study, only approximately one-quarter of detained individuals were involved in a working activity, and almost one-third were involved in social or working reintegration activities; however, the large majority of those participating in these activities found them to be useful. These findings highlight the need to enhance evidence-based interventions promoting healthy lifestyles and working activities in prison.

The results on reported health status and satisfaction with health status have shown that providing effective health services to detained individuals remains a missed opportunity in Italy. Indeed, according to Italian legislation, healthcare services for PDL should be the same as for all citizens. At the time of incarceration, detained individuals have a medical examination, and all information regarding their health status are collected in the medical file. In general, with some territorial differences, health services, including general medicine, nursing, specialistic healthcare, such as dentistry, cardiology, psychiatry, infectious diseases, healthcare of patients suffering from addictive disorders, rehabilitation, and health promotion and screening are provided when needed. Specifically, dental and psychiatric services are carried out within the prison, following a waiting list and are made on request of the primary care physician. However, proactive and preventive interventions, which would likely be more effective in such a population, are not provided on a regular basis.

There is paucity of data on PDL satisfaction with healthcare provided during detention, and this study has added novel knowledge on this issue, identifying some determinants of satisfaction. According to the current results, the higher the health needs, the lower the satisfaction with the healthcare provided because those who reported health problems in the previous year and those who had attempted suicide were significantly less satisfied. This is worrying because dissatisfaction may further reduce demands on health services in a population that is at risk of serious health consequences. The finding that older detained individuals are more satisfied with the healthcare they received may be related to lower expectations compared with younger individuals, whereas the higher satisfaction of those who are in their first detention deserves a more detailed analysis. Indeed, it has been reported that incarceration provides easier access to health services for people who often face substantial barriers to accessing healthcare in the community;[27] therefore, those who are in their first incarceration may perceive the set of healthcare services provided in prison as more satisfactory than those available in the community.

The results demonstrate that there is room for improvement in the healthcare services provided to PDL, given the burden of health problems reported by respondents, involving mainly chronic diseases and dental and emotional health problems. In this context, a key role is played by PDL satisfaction with health status, which is mainly associated with age and reported health problems. Satisfaction with health status is promoted by working activity and is also a determinant of satisfaction with healthcare received.

Limitations

The study has some limitations. Data were collected as cross-sectional, which could have resulted in oversampling of PDL with a longer duration of detention. Moreover, data were collected through a self-administered questionnaire, which could be responsible for misleading interpretation of language content. Another limitation of self-administration was the difficulty in using more detailed questions regarding the number of medical and dental visits, type of medical or dental health problems, as well as the number and time since suicide attempts, which would have allowed a clearer picture of detained persons' health needs. However, this data collection method also allows simple and honest responses. Further research investigating these issues is needed. In addition, enrolled detainees were from three prisons in Southern Italy hosting only male individuals; therefore, the study examines only a subset of the detained population, which, given the large voluntary participation with a very high response rate, are highly representative of the Southern context, but the generalisability of the results to the wider population of PDLs in Italy should be made with caution. Finally, few women are hosted in the prisons in the study area; thus, they were not included in the study, and further research including female PDLs is required.

Conclusions

In conclusion, this study shows that detained male individuals have multiple and frequently unmet health needs. Some of the reported health problems or diseases were present at the time of incarceration, but these often worsened and/or increased during detention, even when NHS healthcare was provided. Prison settings represent a unique opportunity to identify and manage health problems in one of the most vulnerable and disadvantaged groups in the population; therefore, evidence-based interventions to strengthen the role of healthcare services provided in prisons should be promoted. Moreover, given the syndemic characteristics of the health problems in this population, an integrated and multidisciplinary approach, with specific focus on health promotion and primary healthcare, is warranted.

Author statements

Ethical approval

The study was approved by the Ethics Committee of the Local Health Unit Napoli 1 (protocol code: 297) and of the Local Health Unit of Caserta (protocol code: 400).

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Authors' contributions

R.L., G.D.G. and M.P. contributed to conception, edited the design, and developed methodology. R.L. acquired data. G.D.G., C.P.P., G.D.P. and M.P. contributed to statistical analysis and

interpretation of data. R.L. contributed to investigation. G.D.G., C.P.P., G.D.P., R.L. and M.P. contributed to resources. G.D.G., C.P.P., G.D.P. and R.L contributed to data curation. G.D.G., C.P.P. and M.P. wrote the article. M.P. reviewed and edited the article. M.P. contributed to supervision. All authors have read and agreed to the published version of the article.

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Original Research

Preferences of cancer patients as a guide to cancer prevention: a retrospective willingness to pay study in Nepal

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ABSTRACT

Objective: In developing countries, like Nepal, with no population-based cancer registry and low level of awareness, it is difficult to communicate the significance of cancer preventative measures to the general population. Only patients, who have faced or facing the economic and mental burden of cancer, can better understand the importance of early diagnosis. This led us to study the retrospective preference of cancer patients in valuing an annual comprehensive cancer screening program in Nepal.
Study design: This is a primary survey-based study of 600 diagnosed cancer patients (aged 18+ years) randomly sampled from five hospitals of Nepal during December 2015–February 2016.
Methods: Using the contingent valuation estimation methods, we modelled patients' willingness to pay (WTP) for early cancer screening through the Structural Equation Modelling framework.
Results: About 59% of our sampled patients did not receive education and 65% earned below $100/month. Among other findings, we saw that the *Risk of re-occurrence* impacted *WTP* through two opposing channels. The direct effect of *Risk of re-occurrence* on *WTP* was positive ($\beta = 0.20$; $p < 0.05$), but higher the risk of cancer relapses, the higher was the *Pessimism* among patients, which indirectly impacted *WTP* negatively ($\beta = -0.16$; $p < 0.1$). In addition, we found the effect of *Income* on *WTP* to be positive ($\beta = 0.15$; $p < 0.05$), whereas, one belonging to the *Dalit* section of the society had lower *WTP* for screening.
Conclusion: Cancer patients value the importance of early diagnosis with multiple psychosocial factors impacting this preference. This direct account of patients could be used as evidence in policymaking.

Introduction

The International Agency for Research on Cancer (IARC) reported that the global burden of cancer rose to 18.1 million new cases and 9.6 million cancer deaths in 2018 as compared to 14.1 million and 8.2 million, respectively, in 2012. The global pattern suggests that, in 2018, more than half of the cancer deaths worldwide occurred in Asia. In the absence of population-based cancer registries, cancer control management programs in these countries take a backseat.[1–3] The increase in cancer incidences and mortality is attributable mainly to the late diagnosis of the disease, poor prognosis, and treatment.[4] The prognosis of cancer is so slow that individuals are unlikely to feel the symptoms until the disease reaches its advanced stage.[5–7] Late detection decreases patients' survival chances and increases the treatment costs. It is therefore crucial to improve the rate of cancer screening uptake in developing countries such that these abnormalities are detected early on. Noting this challenge, through this paper, we are trying to evaluate the importance of early screening for cancer through retrospective willingness to pay measures. The information generated will create awareness on cancer prevention, will promote the uptake of cancer preventative measures in developing countries, and will simultaneously help in policymaking.

Screening in low- and middle-income countries remain insufficient because of numerous demand and supply side factors.[8] On the demand side, expenses,[9,10] lack of information and awareness,[11,12] inability to perceive the benefits of preventative measures, and sociodemographic characteristics[13] deter an individual from undergoing screening. The supply side constraints, however, are inadequate resources in the health industry,[14–16] and poor organizational structure of hospitals[17] among others. Especially in the emerging economies, reduced access to basic health needs[18,19] and lack of health insurance coverage[20] make the provision and uptake of preventative services even more difficult.

Like most developing countries, Nepal does not have a national-level population-based cancer registry system. Most of the available

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information on cancer in Nepal come from hospital-level case studies with limited demographic information on patients.[21–26] Literature shows an overwhelming, i.e., 8000–10,000 year-on-year increase in the number of cancer cases over the last 10 years.[26] The rise in the cases impose significant financial and non-financial burden to the Nepali society. In 2012, the total productivity loss due to cancer in Nepal was estimated to be $149 million and $121 million among males and females, respectively.[27] This calls for early cancer screening programs in the health landscape of the country.

In developing countries, with low level of information and awareness, it is difficult to communicate the importance of cancer preventative measures to the general population. We hypothesize that cancer patients will have a deeper understanding of the disease adversities and that they would relate more to the true importance of early cancer diagnosis.[28] Therefore, we aim to capture the retrospective preferences of diagnosed cancer patients in valuing an annual comprehensive cancer screening program in Nepal. Our research questions specifically focus on (a) if cancer patients would be (retrospectively) willing to pay for cancer screening program, had that was made available before their diagnosis. In the present context, willingness to pay (WTP) is the maximum amount they would be ready to pay (out-of-pocket) for a comprehensive cancer screening program annually (b) what are the different psychosocial factors that impact one's preference for screening. We use contingent valuation techniques (CV) in analysing the preferences of cancer patients.[5,29,30] Contingent valuation method is used to estimate the monetary values of goods and services that are not traded in the market and hence does not have a market value; we aim to obtain the non-market valuation of such goods through CV.

Almost no literature exists in Nepal with patient-level understanding of cancer complexities. To the best of our knowledge, this is the first study with direct account of cancer patients on their perceptions, beliefs, and experiences of disease adversities post-diagnosis. Amidst the growing interests in understanding the cancer situation in developing countries, the merit of the paper is in its attempt to provide an individual-level overview of cancer patients.

Availability of annual cancer screening programs in the hospitals of Nepal will spread awareness. More importantly, cancer patients' stated preferences for early screening will be instrumental in informing the healthy individuals about better health choices. Already been diagnosed with cancer, our respondents should consider this an opportunity to influence the government decisions with their informed views.[31] Their responses may influence policymakers and could help prevent the future generation from going through similar cancer adversities.

Methods

Participants and study design

The Federal Democratic Republic of Nepal is a landlocked country in South Asia with approximately 28 million population in 2020. Of the 77 districts of Nepal, we have purposively sampled two hospitals from Kathmandu district and one hospital each from Bhaktapur and Chitwan districts for the survey. The reasons being (a) Kathmandu, Bhaktapur, and Chitwan are amongst the top 10 most cancer-affected districts of Nepal; (b) most of the country's specialty cancer hospitals are located in the Kathmandu valley and Bhaktapur districts; and (c) Chitwan district hosts the nation's largest cancer super specialty hospital. A total of 538 cancer patients were randomly sampled for interview from these four hospitals. In addition, we also randomly selected 62 cancer patients from one hospital of the Kavrepalanchok district. Overall, a total of 600 cancer patients were enumerated for the study during December 2015 to February 2016 with a response rate of 97%. We enumerated patients who were aged 18 years and older and were receiving cancer treatment either as an outpatient or inpatient. We excluded any adult patients who were severely disabled to respond on their own.

Informed consent was taken from all the patients and their participation was kept totally voluntary. We maintained their privacy by delinking their personal identifying information from the main data file; their responses were kept fully anonymized and cannot be identified via the paper.

Three separate ethics committees have individually evaluated and approved the study protocol, they are the Institutional Review Board Requirement (IRB) protocols of the University of New Mexico–USA, The Kathmandu University School of Medical Sciences Institutional Review Committee, Nepal, and the Nepal Health Research Council.

We apply the Structural Equation Modelling (SEM) framework to analyse respondent's WTP. An SEM is generally used in a social science research where multiple intertwined variables affect the dependent variable and each other simultaneously. With an extensive set of collinear variables impacting the WTP, it is hard to establish a causally well-defined regression equation. An SEM is suitable to address these complexities. Details of SEM and the variables used for analysis are explained in the later sections.

Variables

The dependent variable for our CV analysis is the *WTP* for the annual comprehensive cancer screening. Before the respondents were asked about their preferences, they were given a brief narration of the cancer situation in Nepal. A script was read out to them, which detailed the gains and tradeoffs involved in paying for such a program. After they heard the script, we engaged them in two rounds of bidding processes through a set of questions.

First, respondents were asked if they were willing to pay an *XX* amount annually towards cancer screening. The *XX* amount was chosen randomly from a set of bids [NPR 500, NPR 1000, NPR 3000, NPR 6000, and NPR 10000].[1] Second, if they have answered *Yes* to the previous question, they were presented with a subsequent bid amount which is double of the initial amount. Whereas, if they have said *No,* they were provided with an amount which is half of the initial bid. For our analysis, we use the maximum WTP values (the highest bid) reported by the respondents, hence our dependent variable became continuous.

With regard to the independent variables used in the model, we have a total of six endogenous and 11 observed exogenous variables. They are specified in Eq (1) and Eq (2).[2] Five of the endogenous variables [*Chances*, *Pessimism*, *Information*, *Optimism*, and *SelfRated*] are latent, whereas, *WTP* is an observed endogenous variable. Finally, the variable *Stigma* is the only latent construct that is exogenous to the model.

The latent variable *Chances* is defined as patients' perceived survival chances from the current state of the disease. A higher value of *Chances* is indicative of higher certainty of survival from cancer. This latent variable is composed of two observed variables: (a) *Absolute chances,* which measures patient's perceived chance of getting completely cured from cancer; (b) *Relative chances,* which measures patient's perceived chance of getting cure relatively to other cancer patients.

Optimism measures patients' faith in the curability of the disease or survivability of cancer patients in general. *Stigma* marks the disgrace/embarrassment a patient feels after being diagnosed with

[1] NPR is the currency of Nepal. NPR 500 was equivalent to USD 5; NPR 1000 = USD 10; NPR 3000 = USD 30; NPR 6000 = USD 60; and NPR 10,000 = USD 100 at the time of the survey.

[2] The observed exogenous variables are as follows: *Familial relationship, Distance, Income, Dalit, Age, Relative Cancer, Ln(Expenses), Screen help, Risk of re-occurrence, Aggressive payment, and Perceived Risk*.

$$\begin{aligned}
&Chances \rightarrow f\,(Absolute\ chances\ of\ cure, Relative\ chances\ of\ cure) + \vartheta_1\\
&Pessimism \rightarrow f(Feeling\ bad, Lose\ hope, Hurting\ oneself\ ) + \vartheta_2\\
&Information \rightarrow f(Knowledge\ of\ screening\ tests, Information\ from\ hospitals\ ) + \vartheta_3\\
&Optimism \rightarrow f(Cancer\ Treatable, Cancer\ survivable\ ) + \vartheta_4\\
&SelfRated \rightarrow f(Content\ of\ QOL, Energetic\ ) + \vartheta_5\\
&Stigma \rightarrow f(Change\ in\ attitude, Feel\ the\ stigma, Hide\ cancer\ ) + \vartheta_6
\end{aligned} \tag{1}$$

$$\begin{aligned}
&WTP = \alpha_0 + \alpha_1 Optimism + \alpha_2 Chances + \alpha_3 Information + \alpha_4 Pessimism + \alpha_5 Stigma + \alpha_6\ SelfRated + \alpha_7\ X + \varepsilon_1\\
&Chances = \beta_0 + \beta_1 Optimism + \beta_2 Information + \beta_3 Pessimism + \beta_4 Risk\ of\ reoccurence + \beta_5 Y + \varepsilon_2\\
&Pessimism = \gamma_0 + \gamma_1 Information + \gamma_2 Risk\ of\ reoccurence + \gamma_3\ Stigma + \gamma_4 Z + \varepsilon_3\\
&Information = \eta_0 + \eta_1 Age + \eta_2 \mathrm{Dalit} + \eta_2 \mathrm{PerceiveRisk} + \varepsilon_4\\
&Optimism = \delta_0 + \delta_1 Information + \delta_2 Z + \varepsilon_5\\
&SelfRated = \pi_0 + \pi_1 Optimism + \pi_2 \mathrm{Dalit} + \varepsilon_6
\end{aligned} \tag{2}$$

cancer. *Stigma* is measured based on three indicators: changes in the attitudes of family member, feeling of embarrassment due to the disease, and patient's need to hide the disease. *Pessimism* defines a state of mind where patients consider their life unworthy to live for. *Pessimism* is measured by the feeling of depression and loss of hope to live life. Feeling energetic and being content with individual's quality of life measures one's *Self-Rated* health. The risk of cancer relapses is measured through the variable *Risk of re-occurrence*. If one believes that cancer can relapse, they attribute a higher value to *Risk of re-occurrence*. Awareness and dissemination of knowledge regarding various causes and symptoms of cancer is captured in *Information*. *Perceived Risk* evaluates if patients ever perceived the risk of getting cancer before diagnosis. Other explanatory variables included in the analysis are Distance to hospitals, Income, Age, Treatment expenses, and their mode of paying among others.

Structural Equation Modelling

A SEM is composed of two types of models: measurement models and structural models. The measurement models specify the relationships between the observed indicators and their underlying latent factors, whereas the structural model measures the causal relationship between those latent variables and the outcome variables.[32–35] The total effect of the independent variables on the structural ones can be decomposed into direct and indirect effects under SEM.

Equation (1) is a set of measurement equations of six endogenous and one exogenous latent variable and Equation (2) is a set of structural equations of six endogenous variables.

Six structural equations and 14 measurement equations are modelled under SEM.[3] The measurement models construct latent factors from observed variables. For example, we test if the observed variable *Absolute chances of cure* significantly predicts its corresponding latent construct *Chances*. The number of measurement equations therefore equals the number of measurement variables. The latent variables are true scores and are not directly observed, whereas the measurement variables are directly observed.

We assume block independence of these two sets of equations, i.e., Eq (1) and Eq (2). But we allow for the error terms of our structural variables under Eq (2) to correlate freely with each other, i.e., the errors of all our endogenous variables (observed and latent) are kept unstructured. This is a crucial assumption under SEM which accounts for potential interdependency or simultaneity between the structural variables.

Results

Sample characteristics

First, we describe the characteristics of the respondents in Table 1. Majority of the patients had no formal education (59%) and 65% of them earned a monthly income below NPR 10,000 (~$100). The female cancer patients constituted 54.4% of the sample. The mean age of our sampled respondents was 52 years, and 16% belonged to the disadvantaged ethnic group of the society (Dalit).[4]

In Table 2, we provide the descriptive statistics of the independent variables used in our model. Most of the patients reported facing stigma due to cancer. About 17% *always* felt that they had lost hope in their survival against the disease. Though a majority of patients (58%) showed *Optimism* and believed that cancer can be treated, they were not content with their quality of life (QOL) (only 11% spoke positively on their QOL). We found that the perceived absolute and relative chances of survival (83%) from the disease were higher among the respondents, even though 11% of them believed that cancer will certainly relapse. A total of 87% of the sampled patients thought that screening test would have been beneficial if was undertaken before.

[3] For brevity, we have only shown a few observed exogenous variables in the model such as *Age*, *Dalit*, *Risk of reoccurrence*, and *PerceiveRisk*, rest of them are clubbed under the *X*, *Y*, and *Z* variables.

[4] During the survey, questions on '*Education*' and '*Income*' were asked in ranges and are used as categorical variables. This increases the accuracy of the responses relative to when asked as a continuous variable. Questions on '*Age*' and '*Treatment expenses*', however, were continuous variables.

Table 1
Sociodemographics variables.

Variables	Definition	Mean	SD
No education	Have no formal education in school	0.59	0.49
Education 1-8th	The highest level of educational attainment is Class 8	0.2	0.4
Education 9-12th	The highest level of educational attainment is Class 12	0.16	0.37
Education >12th	Education beyond Class 12	0.04	0.2
Income <10 k	Individual income < NPR 10,000	0.65	0.47
Income 10-20 k	Income between NPR 10,000 & NPR 20,000	0.19	0.39
Income 20-30 k	Income between NPR 20,000 & NPR 30,000	0.11	0.31
Income >30 k	Income between NPR 20,000 & NPR 30,000	0.05	0.21
Age	Age of the patient	52.37	14.09
Dalit	Belongs to the Dalit section of the society	0.16	0.36
Ln (Expenses)	The logged value of the total treatment expenses	11.02	0.92
Family history of cancer	Any immediate member had a family history of cancer	0.12	0.32

Note: NPR is Nepali Rupees. At the time of writing this paper, 1 $ = NPR 100.

Table 2
Definition of the variables (in percentages).

Variables	Not at all	Several days	More than half days	Nearly every day
Self-rated				
Energetic	54.64	24.45	9.78	11.13
Content QOL	45.7	23.44	19.22	11.64
Pessimism				
Feeling bad	39.12	37.1	14.5	9.27
Lose hope	46.88	22.93	12.98	17.2
Hurting oneself	51.77	27.49	14.84	5.9
Stigma	**Definitely false**	**Probably false**	**Probably true**	**Definitely true**
Stigmatized	63.51	20.44	9.63	6.42
Hide cancer	68.92	16.05	7.77	7.26
Attitude	62.16	22.13	9.29	6.42
Chances	**Mean**		**SD**	
Absolute chances	7.5		2.01	
Relative chances	0.83		0.38	
Optimism				
Cancer survive	0.47		0.5	
Cancer treated	0.58		0.49	
Information				
Information hospitals	0.22		0.42	
Knowledge of test	0.22		0.41	
Risk of re-occurrence	**Between 10 and 30%**	**Between 40 and 60%**	**Between 70 and 90%**	**100%**
	36.09	27.49	24.79	11.64
Other variables	**Mean**		**SD**	
Communication with family	0.34		0.47	
Perceived risk	0.13		0.34	
Aggressive payment	0.52		0.5	
Perceived benefits	0.87		0.34	
Distance (in hours)	**<1–3 h**	**3–5 h**	**55–10 h**	**>10 h**
	44.61	13.64	20.37	21.38

*Absolute chance is an ordered variable. The number 7.5 indicates that the absolute chances of respondents range somewhere between (60%–70%) and (70%–80%).

Results of structural equation models

Table 3 provides the results of structural equations.[5] Under the measurement equations (not shown in the paper), each of the observed variables are found to have a significant loading on the predicted factors. This validates the underlying relationships between the latent constructs and their observed variables.

The structural results show the direct and indirect effects of the variables in relation to *WTP*. As we can see from the standardized coefficients presented below, the direct and the total effects of *Self Rated* ($\beta = 0.73$) and *Chances* ($\beta = 0.20$) are positively associated with *WTP*. The variable *Chances* has been normalized to one. *Optimism* does not directly, rather has an indirect positive and significant impact on WTP. This is because, *Optimism* is correlated with higher chances of getting cure ($\beta_{Optimism\ on\ Chances} > 0$). Also with higher *Optimism*, one self-rates their health better ($\beta_{Optimism\ on\ self\ rated} > 0$); both of which made the indirect effect of *Optimism* on *WTP* positive and significant when the direct effect was indeed negative. Interestingly, this indirect positive effect almost nullified the direct negative effect.

When patients are pessimistic (*Pessimism*), this yields to negative effect on *WTP*. The negative (direct) effect of *Pessimism*

[5] The results of the measurement equations are not shown in the paper due to brevity. The SEM model was fit with clustered robust, the goodness of fit for the model was ascertained by a coefficient of determination of 0.893 and standardized root mean squared residual of 0.048. Given the cross-sectional nature of the data, the effects which might appear to suggest causality are in fact correlational in nature.[36]

Table 3
Total effect of variables on willingness to pay separated into direct and indirect effects.

Structural variable: WTP	Direct effect	Indirect effect	Total effect
Chances	0.20		0.20
Optimism	−0.32	0.31*	−0.01
Information	−0.05	0.04	−0.009
Pessimism	−0.65**	−0.66***	−1.31***
Stigma	0.22	−0.118	0.10
Self-rated	0.73***		0.73***
Income	0.15**	−0.009	0.14***
Dalit	−0.07	−0.060	−0.13***
Risk of re-occurrence	0.20**	−0.16*	0.038
Communication with family	0.13***	0.02	0.15***
Aggressive payment	−0.09**	−0.008	−0.10***
Perceived risk	0.07*	−0.001	0 0.07**

Note: The coefficients are standardized coefficients.
Other observed exogenous variables that are not significant to the model are Age, Relative having cancer, Total treatment expenses, Distances to nearby cancer facility, and whether screening helps.
*$p < 0.1$ (significant at 10% level), **$p < 0.05$ (significant at 5% level), and ***$p < 0.01$(significant at 1% level).
The cells are kept empty if there are no direct and indirect paths linking the corresponding variables.

(β = −0.65) further gets aggravated by the negative (indirect) effects (β = −0.66) leading to a combined total effect of *Pessimism* on *WTP* negative and significant (β = −1.31).

Another interesting insight can be seen from the variable *Risk of re-occurrence*. We see that when patients believe that cancer will likely relapse, they are willing to pay more for any cancer prevention measures. So, the direct effect of *Risk of re-occurrence* on *WTP* is positive ($\beta_{Riskof\ re-occurence\ on\ WTP} > 0$) and significant, but *Risk of re-occurrence* is also directly associated with higher sense of *Pessimism*, i. e., higher the risk of cancer re-occurrence, higher is the pessimism among the patients ($\beta_{Risk\ of\ re-occurence\ on\ Pessimism} > 0$). Increased pessimism, on the other hand, negatively impacts one's WTP as we have seen before ($\beta_{Pessimism\ on\ WTP} < 0$). Therefore, the indirect effect of *Risk of re-occurrence* on *WTP* through *Pessimism* turned out to be negative, even though the direct effects are positive. The latent variable *Pessimism* here acted as a moderator. This way, we see two opposing channels of *Risk of re-occurrence* impacting WTP; the first being, the positive direct effect and the second is the negative indirect effect. This is illustrated in Fig. 1.

With regard to the demographic variables, we see that patients belonging to the higher economic category are likely to pay more for the good [*Income* (β = 0.14)], whereas those who have already borrowed money or have sold properties for treatment are significantly less likely to have agreed to pay for further screening ($\beta_{AgPay=}$ − 0.10). *Dalit* represents the lowest sociodemographic class of the society in Nepal, their direct effect on *WTP* is negative. Their availability to cancer preventative information is significantly less ($\beta_{Dalit\ on\ informaiton} < 0$), making the indirect effect of *Dalit* on *WTP* also negative. Given both the direct and indirect effects of *Dalit* on *WTP* is negative, the total effect remained significant (β = −0.13).

Next, we discuss the *Direct* and *Indirect* effects observed on other variables in Table 4. We find that *Optimism* significantly increases with *Information* (β = 0.42). Higher optimism is observed among economically richer strata of the society (β = 0.07). As also been seen before, higher *Pessimism* among patients give rise to lower *Self-rated* chances of cure and the result is significant (β = −3.19). Increase in *Age* and being in the socially disadvantaged group of the society (*Dalit*) reduces one's access to information (β = −0.30). Finally, we see that as *Risk of cancer re-occurrence* increases among patients, it leaves them with higher amount of *Pessimism* (β = 0.189). Indirect effects that turned out to be significant are also shown in Table 4.

Discussion

We know that burden of cancer mortality is increasing in low- and middle-income countries. Despite of the substantial evidences

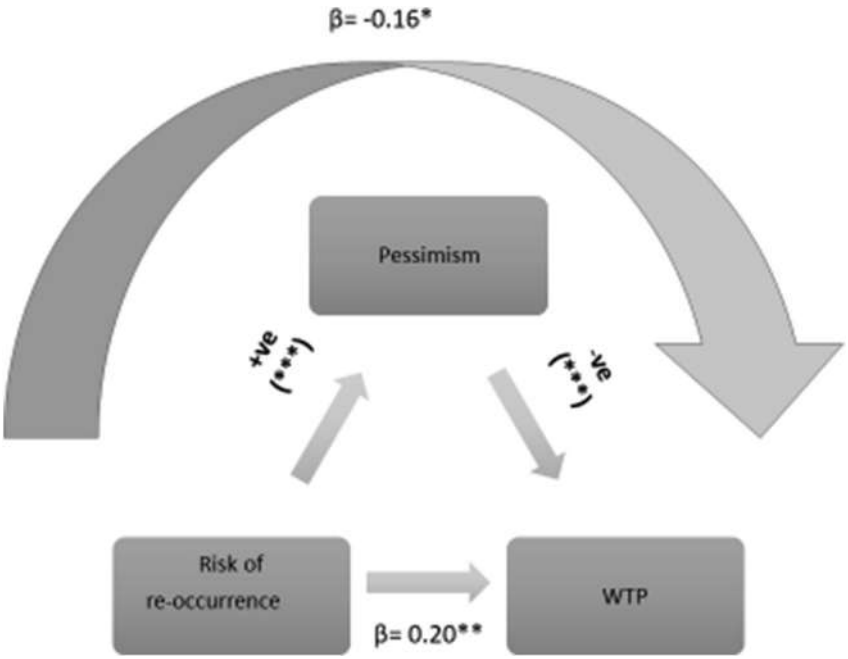

Fig. 1. Pessimism as a mediator between Risk of re-occurrence and WTP. Results from Structural Equation Modelling are presented in this figure. *$p < 0.1$ (significant at 10% level), **$p < 0.05$ (significant at 5% level), and ***$p < 0.01$ (significant at 1% level). +ve indicates that Risk of re-occurence significantly increases Pessimism in cancer patients. -ve indicates that Pessimism significantly decreases *WTP*. The direct effect of Risk of re-occurrence on *WTP* is positive and significant (β = 0.20**). The curved arrow from *Risk of re-occurrence* to *WTP* shows the indirect effect of *Risk of re-occurrence* on *WTP*, through the mediator effect of *Pessimism*. This indirect effect is negative and significant (β = −0.16*).

Table 4
Direct and indirect effects of other model variables.

Direct effects	
Information on Optimism	0.42**
Income on Optimism	0.07**
Pessimism on Chances	−3.19***
Dalit on Information	−0.133***
Screen help on Optimism	0.15***
Age on Information	−0.300***
Perceive risk on Information	0.18**
Risk of re-occurrence on Pessimism	0.189***
Relative cancer on Optimism	0.11**
Indirect Effects	
Information on Self-rated *(Information on Optimism on Self-rated)*	0.12**
Dalit on Optimism *(Dalit on Information on Optimism)*	−0.055**
Age on Optimism *(Age on Information on Optimism)*	−0.12**
Risk of re-occurrence on Chances *(Risk of re-occurrence on Pessimism on Chances)*	−0.60*
Stigma on Chances *(Stigma on Pessimism on Chances)*	−0.60*
Perceive risk on Optimism *(Perceive risk on Information on Optimism)*	0.07**

*$p < 0.1$ (significant at 10% level), **$p < 0.05$ (significant at 5% level), and ***$p < 0.01$(significant at 1% level).

demonstrating the effectiveness of cancer screening tests both in developed[39–41] and developing countries,[42–44] late-stage diagnosis of cancer remains a significant risk factor to cancer mortality.[6,7,37,38] We also know that the level of awareness and knowledge on cancer preventative measures are limited in low-income countries. Therefore, it is important to create information such that the general population can be made aware of the significance of early cancer diagnosis.

In this paper, information is generated by measuring the retrospective preferences of diagnosed cancer patients who are currently under treatment in Nepal. The study was conducted among 600 cancer patients across five hospitals of Nepal. The patients were asked if they would have been willing to pay for early cancer screening tests if that were made available to them before. However, in a resource-poor country like Nepal, undergoing screening tests through out-of-pocket expenditure is subjected to budget constraint. Noting this tradeoff, we modelled the various psychosocial factors that determine a patient's willingness to pay for cancer screening.

The structural results presented in Table 3, Table 4, and Fig. 1 show the direct and indirect effects of independent variables on *WTP* and on each other simultaneously. We find that variables like *Self-Rated* ($\beta = 0.73$) and *Chances* ($\beta = 0.20$) are positively associated with *WTP*. Whereas, *Pessimism* ($\beta = -0.66$) leaves both a direct and indirect negative effects on *WTP*, leading to a combined total effect of *Pessimism* on *WTP* negative and significant ($\beta = -1.31$).

Interestingly, we find instances where latent construct (*Risk of re-occurrence*) impacts outcome variable (*WTP*) through two opposing channels. For example, when individuals believe that there is a higher chance of cancer re-occurrence (*Risk of re-occurrence*), they show a higher (positive) willingness to pay for cancer screening as shown in Table 3 ($\beta = 0.20$**).[6] *Risk of re-occurrence*, on the other hand, is also directly associated with higher sense of *Pessimism* shown in Table 4; the higher the risk of relapses of cancer, the higher is the *Pessimism* ($\beta = 0.189$***). However, from Table 3, we see *Pessimism*, negatively and significantly impacts one's *WTP* ($\beta = -0.65$**). Through this mediator effect of *Pessimism*, the indirect effect of *Risk of re-occurrence* on *WTP* turned out to be negative, even though the direct effects are positive (as illustrated in Fig. 1). This opposing direct and indirect effects are called mediation with suppression. We also find that higher income increases whereas belonging from a lower section of the society (*Dalit*) with lower information decreases one's willingness to pay.

Similar analysis on the likelihood of genetic testing for cancer and the factors impacting willingness to pay is done by Bosompra et al.,[36,45] in the context of US. They however find that likelihood of testing is positively related to having a generally pessimistic outlook on life, whereas, Optimism reduces one's susceptibility to cancer and hence was associated with reduced likelihood of screening. Though our findings differ from Bosompra et al., both these set of results equally contribute to the literature. This is because, the sample that Bosompra et al. analysed was that of the general population, whereas our sample composed of diagnosed cancer patients who were stating their retrospective preferences for screening.

We believe that this paper will act as a source of information to the general individuals as well as to the policymakers on the importance of early screening. The stated preferences of cancer patients will potentially yield to more demand and uptake of routine screening of cancer. Policymakers should view the perspective of cancer patients as a guidance to bring in cancer control measures in the country. Initiation of such programs in the hospitals in itself will spread awareness regarding service availability.

As opposed to the previous studies that captured the willingness to pay for a hypothetical drug guaranteeing 100% prevention from cancer[46] or imaginary pill towards complete remission of the disease,[47] we took a more realistic and informative path of creating information through measuring the preferences of cancer patients.

However, unlike other willingness to pay studies, we did not delve deeper into the mean value of WTP. This is because, our paper does not reflect the demand or preferences of screening tests among the general population; quite contrary, it is only reflective of cancer patient's positive preferences for a preventative health intervention. This, we acknowledge to be a limitation of the retrospective study design.

We also understand that Nepal is beset with inadequate supply of medical resources, any policy proposition to advocate cancer screening in an already resource-constrained economy (as in many South Asian countries) needs targeted policies only on high-risk individuals. Our paper did not have the scope to delve deeper into this targeted policy approach with our limited sample of hospitals and patients. But it provides suggestive evidences highlighting the need of health policies to address the emerging trend of non-communicable diseases in the total disease burden of the country.

Author statements

Ethics approval

Three separate ethics committees have individually evaluated the study protocol. The Institutional Review Board Requirement (IRB) protocols of the University of New Mexico–USA, The Kathmandu University School of Medical Sciences Institutional Review Committee, Nepal, and the Nepal Health Research Council have provided the approval for this study.

[6] In this case, the results are significant at 5% significance levels. Here, we explain the asterisks using their *P*-values and associated significance levels: *$P < 0.1$ (significant at 10% level), **$P < 0.05$ (significant at 5% level), and ***$P < 0.01$(significant at 1% level).

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Competing interests

The authors do not have any conflict of interest.

Availability of data and material

The authors hold the proprietary right to the data.

Consent to participate

Informed consent was taken from all the patients who participated in the study and their participation was kept totally voluntary.

Consent for publication

We maintained the privacy of the patients by delinking their personal identifying information, their responses have been fully anonymized and they cannot be identified via the paper. The consent statement had stated that their responses will be used for research purposes.

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Short Communication

Public misperceptions of COVID-19 vaccine effectiveness and waning: experimental evidence from Ireland

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ABSTRACT

Objectives: The study set out to measure public understanding of COVID-19 vaccine effectiveness (VE) and how effectiveness wanes with time since vaccination. Because perceived VE is a strong predictor of vaccine uptake, measuring perceptions can inform public health policy and communications.
Study design: Online randomised experiment.
Methods: The study was undertaken in Ireland, which has high vaccination rates. A nationally representative sample (n = 2000) responded to a scenario designed to measure perceptions of COVID-19 VE against mortality. The length of time since vaccination in the scenario was randomly varied across four treatment arms (2 weeks, 3 months, 6 months, and 9 months).
Results: The public underestimates VE, with substantial variation in perceptions. A majority (57%) gave responses implying perceived VE against mortality of 0–85%, i.e., below scientific estimates. Among this group, mean perceived VE was just 49%. Over a quarter (26%) gave responses implying perceived VE greater than 95%, i.e., above scientific estimates. Comparing the four treatment groups, responses took no account of vaccine waning. Perceived VE was actually higher 9 months after vaccination than 2 weeks after vaccination.
Conclusion: Despite high vaccination rates, most of the public in Ireland underestimates VE. Furthermore, the general public has not absorbed the concept of vaccine waning in the months following vaccination. Both misperceptions may reduce vaccine uptake, unless public health authorities act to correct them through improved communication.

Introduction

High vaccine effectiveness (VE) has been a vital component of humankind's response to the COVID-19 pandemic. In addition to ensuring good protection from disease, high VE increases the incentive for individuals to take vaccines. However, the strength of this incentive is likely to depend on public perceptions of VE.

Although multiple factors contribute to willingness to take COVID-19 vaccines, there is good evidence that perceived effectiveness is a strong determinant. In surveys undertaken across multiple countries before the licensing of COVID-19 vaccines, intention to take the vaccine depended on prospective VE.[1] Initial vaccine hesitancy is associated with low knowledge about VE.[2] The proportion of hesitant individuals has been systematically linked with information provided about VE.[3,4] Experimental manipulation of VE in public health messaging has a positive influence on stated intentions to get vaccinated.[5,6] Changes in perceptions of VE have been associated with higher likelihood of intention to take the vaccine and self-reported vaccination behaviour in longitudinal data.[7] Given this accumulation of evidence, the starting point of the present study is that perceptions of VE are likely to be a factor in people's ongoing decisions to take COVID-19 vaccines and, therefore, that public perceptions of VE are likely, at least in part, to determine the success of continuing COVID-19 vaccination campaigns.

Among people who have already been vaccinated, willingness to take additional doses is also likely to vary with perceptions of how protection wanes. We know of no study that has measured public

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perceptions of vaccine waning, or its relationship with vaccine intentions or behaviour.

Given the above, we set out to measure perceptions of VE and how VE wanes over time via a randomised experiment with a large, nationally representative sample.

Methods

The randomised experiment was conducted in Ireland, with a sample of 2000 adults who participated in an online survey between May 31st and June 21st, 2022. Ireland has one of the higher rates of COVID-19 vaccination in Europe, according to the European Centre for Disease Prevention and Control.[8] Participants were recruited from existing panels of online survey respondents held by two national market research companies (RED-C Research, www.redcresearch.ie; Behaviour & Attitudes, www.banda.ie). The study was inserted into two waves of an existing survey, Ireland's Social Activity Measure (SAM). SAM was a fortnightly study of 1000 adults, which ran from January 2021 until June 2022 and measured levels of social activity and perceptions of the pandemic.[9] Sampling was by quota to match the adult population (aged 18 years and older) of Ireland by sex, region, age and social grade. Table A1 in the appendix presents detail on the sociodemographic characteristics of the sample. Socio-economic indicators were educational attainment, employment status and 'social grade', which is a classification system based on the occupation of the chief income earner of the participant's household.[10] We aimed to match quotas based on the proportion of households in higher, intermediate and junior managerial/professional roles (ABC1) and those in manual or causal work or unemployed (C2DE). The sample closely matches the most recent Irish Census of Population, with a slight (c. 5 %-point) under-representation of adults aged 18–39 years relative to adults aged 40–59 years.

Given time pressures for gathering data during the pandemic, online panels have clear advantages but could, in principle, be more prone to selection biases than probability samples. Empirically, following improvements in internet penetration and online panel construction, close correspondence across survey modes has been recorded.[11,12] Any selection bias in our sample would be more relevant to the absolute measures of VE than to the relative measures across experimental conditions. More generally, despite large changes to online activity and behaviour, direct evidence supports the validity of online survey experiments conducted during the pandemic.[13]

The primary methodological challenge was to design a survey question that both minimised ambiguity and could be understood without specialist medical or statistical expertise. We know of no established method for measuring perceived VE in the general population. We therefore designed a question to measure an individual's perception of VE for COVID-19 vaccines based on a combination of established literature in judgment and decision-making and an informal pilot intended to identify any ambiguity.

For simplicity, we focused on VE against death following exposure to COVID-19. Prior evidence has established that the concepts of sampling, conditional probability and relative risk are challenging for many people.[14] The question was therefore expressed in the form of a simplified numeric counterfactual. Given pressures of time, the question was then piloted informally online, using a convenience sample of approximately 25 professional contacts, friends and family members, who were asked to respond to the question and highlight any ambiguity or difficulty understanding the meaning or intention of the question. This process led us to pose the question in the form of a narrative, avoiding the expressions 'fully vaccinated' and 'booster', because there was confusion over whether these referred to second, third or fourth doses. Since the total number of doses an individual required to be fully vaccinated also varied according to the original vaccine taken, we did not specify the type of vaccine in the narrative.

The final question was as follows:

> *Please imagine the following story. There were 100 people who were exposed to COVID-19 within the past two months. They became infected and unfortunately did not survive. None of the 100 had taken a COVID-19 vaccine.*
> *Now suppose instead that exactly the same 100 people had all taken an approved vaccine* ***[two weeks/three months/six months/nine months]*** *before they were exposed to the virus.*
> *How many of the 100 who died do you think would instead have survived?*

The software randomised participants into four conditions, with all aspects identical except the 'treatment', which was the time since vaccination (in bold).

We chose not to give detail about who the 100 individuals were, since to do so would raise concepts of sampling that some respondents would find difficult. Piloting suggested that participants would understand this scenario as a simple comparison, in general, of the likelihood of death between unvaccinated individuals and individuals who had taken whichever course of vaccinations had been recommended to them. The response box required an entry but was left open, allowing people to write comments or qualifiers as well as numbers. This provided indications of whether some respondents felt that the question was ambiguous, confusing or otherwise unreasonable. Due to the randomised design, alternative interpretations were equivalent across conditions.

For comparison with the public responses, scientific estimates of VE are, of course, imprecise and depend on the relevant SARS-CoV-2 variant. Large sample cohort studies that estimate VE against severe COVID-19, hospitalisation or mortality from two weeks after vaccination have typically ranged from 85 to 95%, even for those at high risk.[15–17] Estimates of VE waning over time fall in the range 8–25 percentage points over 4–8 months.[15,16,18,19] At the time of data collection, the Omicron variant had become dominant in Ireland. While somewhat lower estimates of VE against infection have been recorded in relation to the Omicron variant, VE against severe disease and death appears similar.[20] While these figures are estimates and may change with further research, they reflect contemporaneous scientific understanding and provide benchmarks for comparison of public perceptions.

Results

Of the 2000 participants, 1821 (91%) provided a number between 0 and 100. The 9% non-response rate was consistent across treatments. Most non-responses consisted of 'don't know' or similar. Just 20 responses (1%) complained about the question wording (6 responses) or that the answer depended on information not provided (14 responses, mostly mentioning the ages of the 100 people). Non-responses were excluded.

Of usable responses, the majority (57%) provided responses of 0–85, below the benchmark described above. There was high variability, with 29% of responses at 50 or below and just over a quarter of responses (26%) above 95. The mean response was 69. Overall, therefore, VE was underestimated relative to the scientific benchmark, with substantial variability.

Fig. 1 indicates how responses varied by treatment group. Mean responses (1a) indicate no tendency to account for waning VE. The somewhat higher mean for longer compared to shorter durations since vaccination is short of statistical significance (Kruskal–Wallis,

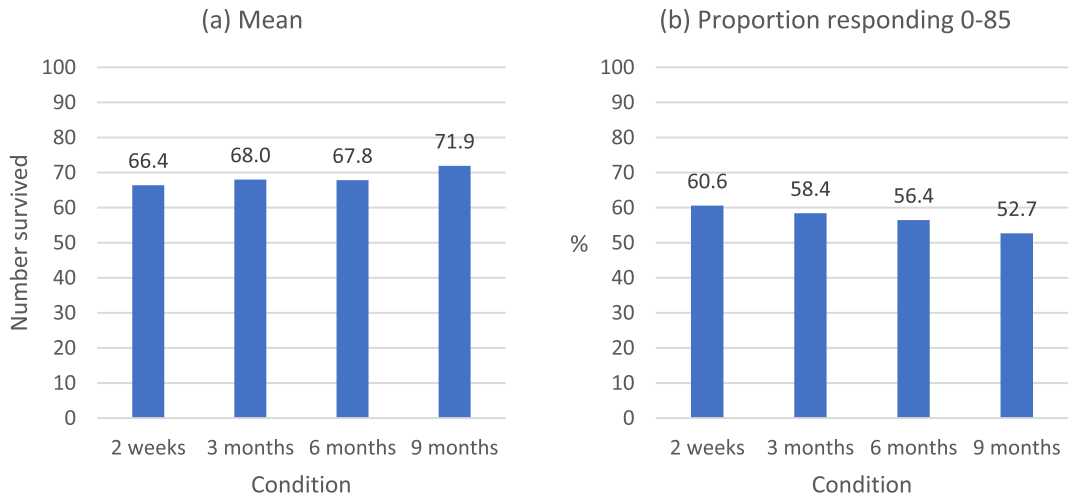

Fig. 1. (a) Mean response by condition; (b) proportion of respondents in each condition who gave a response of 0–85, i.e., below the scientific benchmark.

$P = 0.144$). The proportion providing a response in the range 0–85 (1b) was lower for longer compared to shorter durations since vaccination. Logistic regression of whether participants gave a response in the range 0–85 on treatment group, controlling for sex, age, educational attainment (5 categories) and vaccination status, suggests that low responses were significantly more likely in the shortest duration (2 weeks) condition than in the longest duration (9 months) condition compared to the ($P = 0.015$). In other words, if anything, participants perceived the opposite of VE waning.

We tested for differences in response by various sociodemographic characteristics, including sex, age, educational attainment and rural versus urban residential location. The only background characteristic to display a statistically significant relationship with the response was age. Fig. 2 shows this effect, with responses pooled across treatment conditions. Mean responses (2a) show that people aged 60 years and over believed, on average, that the vaccine would save 6 more lives out of 100 than people aged 18–39 years – a significant difference (Kruskal–Wallis, $P = 0.015$). However, with a mean estimate of 72, this more vulnerable group's perception of VE was still well below scientific estimates. The proportion providing a response in the range 0–85 (2b) was also lower for the oldest group (logistic regression, $P = 0.05$), although the majority remained below the scientific benchmark. Furthermore, responses to the different treatment conditions among older people suggested that, in common with the rest of the sample, they perceived no VE waning up to 9 months.

Discussion

These data suggest that in a country with a high vaccination rate by international standards, the majority of the general public underestimate VE. While around one-quarter overestimate VE, underestimation is more common. Importantly, public perceptions of VE do not account for waning protection over a 9-month period. Although the latter finding might be taken to imply that many people overestimate VE over longer durations, the important point to note is that both misperceptions could reduce the inclination for people who have already been vaccinated to take additional doses. This is, firstly, because they (on average) underestimate VE and, secondly, because they believe they have higher immunity from their previous dose. As outlined in the Introduction, although there is existing evidence to support a link between perceived VE and willingness to take a COVID-19 vaccine, we are not aware of previous evidence in relation to perceptions of how protection wanes or how these influence willingness to take the vaccine.

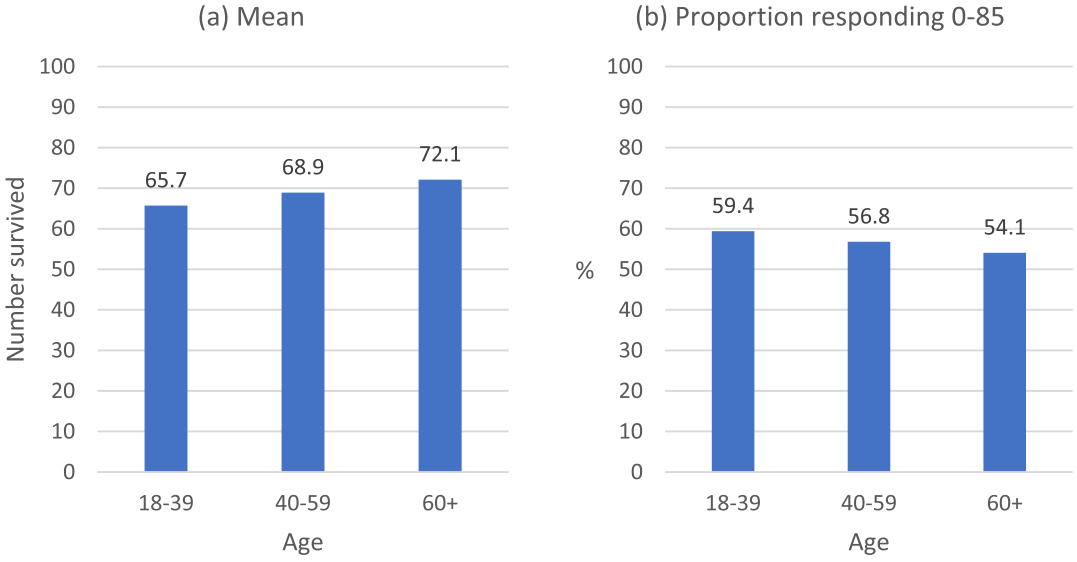

Fig. 2. (a) Mean response by age; (b) proportion of respondents by age who gave a response of 0–85, i.e., below the scientific benchmark.

Given the additional vulnerability of older people to COVID-19, some comfort can be taken from the fact that those older than 60 years had somewhat more accurate perceptions of VE than younger adults. However, even this older group still underestimated VE by a substantial amount. It is also notable that there were no significant differences in responses by educational attainment, given the inherent complexity of the numeric counterfactual scenario that respondents were asked to contend with.

Experiments and surveys that aim to measure public perceptions of quantitative scientific phenomena must inevitably present simplified questions and scenarios. While the research team put much effort into the question wording used here, it remains possible that participants in this study misinterpreted the question in some systematic way, although entries in the open text response box provide some comfort that the large majority intuitively understood what they were being asked. Future research might seek to compare this question with alternative methods for measuring public perceptions of VE.

Perceptions of VE continue to be important in combatting COVID-19. The current findings have relevance for ongoing efforts by public health authorities and governments to increase vaccination rates and to ensure that people take booster doses. Failure to understand VE waning may also have behavioural implications if people, especially vulnerable people, underestimate how their exposure to risk from social activity changes over time. Continued communication of the high rate of VE against severe illness and death, together with the time-course over which it wanes, appears warranted.

Author statements

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Ethical approval

Ethical approval for this study was obtained in accordance with the ethics policy of the Economic and Social Research Institute (ESRI). Informed consent was obtained from participants online, before participation.

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Competing interests

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.11.002.

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Short Communication

Rapid rise in COVID-19 among young people in England – learning for the future

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ABSTRACT

Objectives: We determined the age and sociodemographic distribution of COVID-19 cases between January and September 2020 to identify the group with the highest incidence rates at the beginning of the second wave in England.
Study design: We undertook a retrospective cohort study design.
Methods: SARS-CoV-2 cases in England were linked with area-level socio-economic status indicators using quintiles of the Index of Multiple Deprivation (IMD). Age-specific incidence rates were stratified by IMD quintile to further assess rates by area-level socio-economic status.
Results: Between July and September 2020, SARS-CoV-2 incidence rates were highest amongst those aged 18–21 years, reaching rates of 213.9 (18–19 years) and 143.2 (20–21 years) per 100,000 population by week ending 21 September 2022. Stratification of incidence rates by IMD quintile evidenced that despite high rates observed in the most deprived areas of England amongst the very young and older age groups, the highest rates were observed in the most affluent areas of England amongst the 18- to 21-year-olds.
Conclusions: The reversal of sociodemographic trend in COVID-19 cases in England for those aged 18–21 years at the end of the summer of 2020 and beginning of the second wave showed a novel pattern of COVID-19 risk. For other age groups, the rates remained highest for those from more deprived areas, which highlighted persisting inequalities. Combined, this demonstrates the need to reinforce awareness of COVID-19 risk for young people, particularly given the late inclusion of the 16–17 years age group for vaccination administration, as well as continued efforts to reduce the impact of COVID-19 on vulnerable populations.

Introduction

Following the peak in the first COVID-19 wave in late April 2020 in England, incidence steadily declined after the introduction of a suite of non-pharmaceutical interventions (NPIs) by the UK Government. Throughout the months of March to May, the highest incidence rates of COVID-19 were seen in those aged ≥80 years; there were also disproportionately higher rates among men, people of Black, Asian and Minority Ethnicities and people living in the most deprived areas of England.[1]

Incidence rates declined until late June, after which an accelerated rise was noted in August, accompanied by a marked shift in the age distribution of cases. Here, we describe the epidemiological patterns in COVID-19 rates by age group and area-level deprivation between July and September 2020.

Methods

Data sources

COVID-19 is a notifiable disease in England, and positive tests are reported from public health, National Health Service (NHS) and

Abbreviations: NPIs, Non-pharmaceutical interventions; IMD, Index of Multiple Deprivation; ONS, Office for National Statistics'.

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private laboratories performing SARS-CoV-2 testing. These data are collected using the Second Generational Surveillance System, a routine national laboratory-based surveillance system for notifiable diseases.[2] The address of each case of COVID-19 was assigned using their NHS Digital Patient Demographic Service record. Area-level socio-economic status was defined using quintiles of the Index of Multiple Deprivation (IMD),[3] a measure of relative deprivation; these data were linked to the residential lower super area (small-area geographical unit with an average population of 1614)[4] of each patient. Cases with specimen dates between 27 January 2020 and 27 September 2020, inclusive, comprised the final data set.

Study design

A retrospective cohort study design was used to determine age-stratified COVID-19 rates over the study period between January to September 2020. After identifying the peak age groups, we further stratified these into 2-year age groups to examine incidence rates and test positivity, particularly for the second wave, which began from week of 29 June 2020. We also examined trends by IMD quintiles and region of residence.

Results

Between July and September 2020, COVID-19 rates increased across all age groups, but to the largest extent in 20- to 29-year-olds; among whom the weekly rate increased 10-fold from 9.3 to 95.5/100,000 population (Supplementary Fig. 1). There was also a surge in incidence among those aged 10–19 years with the second highest rate (75.9/100,000) in the week of 21 September.

Among young people, the highest rates were in those aged 18–19 years (213.9/100,000 population) and 20–21 years (143.2/100,000 population) in the week of 21 September (Supplementary Fig. 2A). Although testing rates also increased,[1] test positivity was highest in 18–21 years (Supplementary Fig. 2B).

From mid-August 2020 to the end of the study period, the highest rates in 18- to 19-year-olds nationally were reported in those from the least deprived quintile; among 20- to 21-year-olds, the rates in those from the least deprived quintile increased to the largest extent and, as of September 2020, exceeded but were similar to those from the most deprived quintile (Fig. 1). The inverse relationship between deprivation and cumulative rates among 18- to 21-year-olds observed in all regions of England except Yorkshire and the Humber (Supplementary Fig. 3). The relative shift in rates by IMD quintile was not observed among people of other age groups, where the highest rates have consistently been among those from the most deprived quintile (Fig. 1). While a marked deprivation gradient was observed in other age groups, this was not seen in the 18–21 years group (Fig. 1).

Discussion

In the summer of 2020, COVID-19 cases increased sharply in England, with the highest incidence rates among 18- to 21-year-olds at the beginning of the autumn. During this period, although the overall COVID-19 rates (in people of all ages) were highest among people living in the most deprived areas of England, the highest age-specific rates for 18- to 21-year-olds were among those living in the least deprived areas. However, there did not appear to be a marked difference between deprivation quintiles for this age group. In comparison, there was a clear gradient for other age groups, with the highest rates observed in the most deprived quintile and the lowest rates in the least deprived quintile.[1]

This analysis included comprehensive, individual-level data from the national COVID-19 surveillance system linked to a robust measure of socio-economic status; it therefore included all cases in

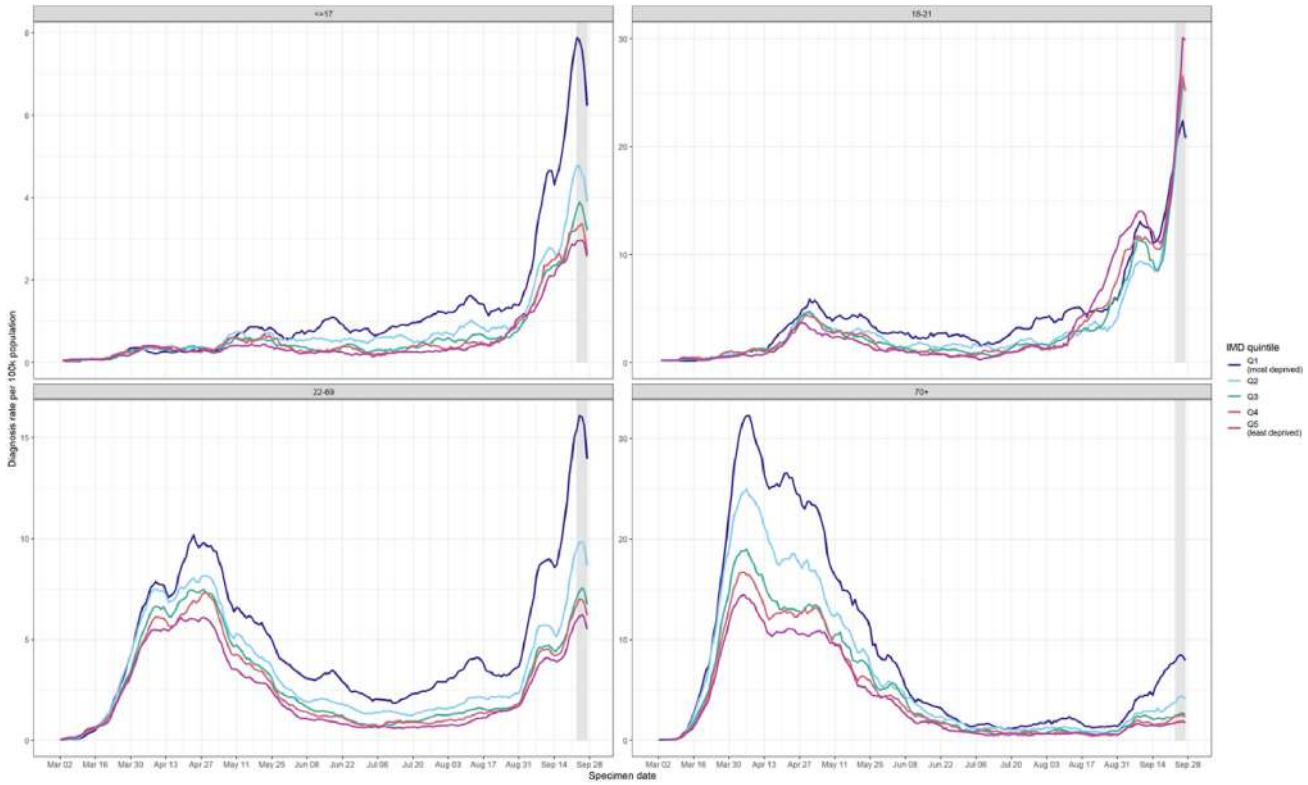

Fig. 1. Rolling 7-day average incidence rates of COVID-19 by Index of Multiple Deprivation quintile and age group, 2 March to 29 September 2020, England.

England and is not subject to the selection bias inherent to survey sampling. The limitations of this study include lack of information on the reasons for COVID-19 testing, including travel history or whether testing occurred because of contact tracing. In addition, due to the absence of population data by ethnicity, age group and IMD quintile, we could not determine rates combining these factors, which would have provided further details on potential inequalities in COVID-19 rates. Although IMD is widely used in England for research, it is a measure of area-level, rather than individual-level, socio-economic status and is therefore subject to the ecologic fallacy. Finally, 18- to 21-year-olds can be a mobile population, and their case details may be attributed to previous residential geography if recent relocations are not yet reflected in their NHS records. However, there is evidence that family socio-economic status can have an impact on longer-term outcomes and might be a reliable indicator of deprivation level, resources and accessibility.[5]

Surveillance data until mid-May 2020 highlighted older people and people living in the most deprived areas of England as higher risk groups, which likely reflected the prioritisation of testing at that time.[3] There is evidence that COVID-19 testing rates in young people disproportionately underestimated incidence in March and April, as seroprevalence reported from the REACT-2 study in late June was highest among people aged 18–24 years (6.9%), most of whom were not tested when they were experiencing symptoms.[6]

The increased detection of COVID-19 among younger people, mainly those aged 20–29 years, was also reported in other European countries, such as Austria, Croatia, the Netherlands and Norway, at the end of the summer 2020.[7] In England, the risk of infection may have changed disproportionately between different age groups and socio-economic backgrounds due to differential changes in behaviour during the easing of NPIs, including activities such as more frequent or larger social gatherings, or overseas travel in the summer holiday season.[8] Our results substantiate findings from a smaller number of cases detected through the Office for National Statistics' COVID-19 Infection Survey, which highlighted increased positivity among those aged 17–24 years and for those aged <35 years from less deprived areas.[9]

Young people reported higher anxiety, depression and loneliness during and after periods of lockdown.[5] Desire for access to supportive social circles and a feeling of normalcy may contribute to less strict adherence to recommended precautions, both throughout the summer of 2020 and potentially in response to future NPIs.[10] Further monitoring of the underlying risk factors for infection in young people, as well as severe or long-lasting outcomes such as long COVID, will become of increasing importance as we adapt to this next phase of mitigating the transmission of COVID-19.

Furthermore, given sustained higher rates overall in people living in the most deprived areas, ongoing, proactive monitoring of the relationships between deprivation and COVID-19 infection should be prioritised to ensure public health measures and policies are delivered equitably.

This study has highlighted the importance of monitoring the effect of changes in NPIs on the relationship between age-specific groups and deprivation to inform public health action during the continued COVID-19 pandemic as well as in future pandemics and outbreaks of respiratory viruses.

Author statements

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Ethical approval

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Competing interests

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2023.01.001.

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Original Research

Regulation of gambling in Sub-Saharan Africa: findings from a comparative policy analysis

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ABSTRACT

Objectives: Commercial gambling markets have undergone unprecedented expansion and diversification in territories across Sub-Saharan Africa (SSA). This gambling boom has popularised the uptake of gambling products in existing circuits of popular culture, sport and leisure and raised concerns about the extent to which state legislation is equipped to regulate the differentiated impacts of gambling on public health.

Study design: Comparative policy analysis.

Methods: This article provides a systematic mapping of the regulatory environment pertaining to gambling across SSA. The review was conducted by obtaining and triangulating data from a desk review of online materials, consultation with regulatory bodies in each territory and the VIXIO Gambling Compliance database.

Results: Gambling is legally regulated in 41 of 49 (83.6%) SSA countries, prohibited in 7 (14.3%) and is not legislated for in 1 (2.0%). Of those countries that regulate gambling, 25 (61.0%) countries had dedicated regulators and 16 (39.0%) countries regulated via a government department. Only 2 of 41 (4.9%) countries have published annual reports continuously since the formation of regulatory bodies, and 3 (7.3%) countries have published an incomplete series of reports since the formation. In 36 (87.8%) countries, no reports were published. Enforcement activities were documented by all five regulators that published reports.

Conclusion: The review uncovered a lack of coherence in regulatory measures and the need for more transparent public reporting across SSA territories. There are also variations in regulating online products and marketing, with most countries lacking apt guidelines for the digital age. Our findings suggest an urgent need to address the regulatory void surrounding online forms of gambling and the promotion of gambling products. This underlines the importance of a public health approach to protect against an increase in gambling-related harms.

Introduction

With the advent of the internet and digital technologies, the global gambling landscape has been transformed in recent decades. In the majority of the world, it is now possible to access casinos, sports books, lotteries, e-gaming and online slots via smartphone technologies that enable rapid forms of real-time play around the clock.[1] This unprecedented expansion and diversification of commercial gambling markets has, however, engendered public health concerns, with many academics, politicians and policymakers cautioning against the detrimental consequences associated with gambling harms.[2,3] As public debate and scrutiny over the regulation of the gambling industry in the 'Global North' has increased,

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researchers have also raised concerns about industry expansion into new markets in the 'Global South', and Sub-Saharan Africa (SSA) in particular, noting the similarities between these trends with those of the tobacco industry when faced with tobacco control.[4,5]

According to VIXIO Gambling Compliance reporting, Africa has become the only continent where sports games account for the majority of all lottery group sales: in 2017, sports made up 52.2% of the turnover of all African lottery operators.[6] Across SSA, the democratisation of access to mobile app and money technologies has provided a viable platform and model for commercial gambling operators to popularise cellular-based vending.[7] New products are frequently driven by European sporting events[8] and technologies provided by companies based in Europe, whereas models of operation enlist local community members in ways that resemble indirect rule strategies from the colonial era. All these trends suggest that the gambling industry in SSA has neocolonial characteristics[9] but also becoming increasingly embedded in local/global gambling markets and infrastructures.[10]

Research examining the public health impacts of commercial gambling activities across the continent has proliferated in recent years. Such work has predominantly focused on the differentiated impacts among young people,[11–14] including how gambling has become embedded in the rhythms of everyday life and sociability for many young people,[15–18] as well as how it is bound up with relations of work, notably with un- and under-employment, precarious work and the absence of viable livelihood opportunities.[19,20] Others have shed light on the sociocultural consumption of gambling; how it is closely tied to the popularity of European football,[21,22] has strong associations with the French horse racing industry,[23] its association with alcohol consumption,[24] how gambling has become normalised particularly in urban environments due to high visibility both in everyday spaces and in media[7,10] and how this may have a range of harmful impacts on mental health, household budgets and interpersonal relationships.[9,25,26]

A recent systematic review of youth gambling practices and problems in SSA noted a paucity of robust studies that assess the prevalence of problem gambling but found high levels of lifetime gambling (57%–73%) among the reviewed study populations.[11] The limited data on gambling problems uncovered by the review reported that 9.6% of a sample of 261 urban Ethiopian adolescents were compulsive gamblers[27] and that 91% of gamblers in a sample of 246 urban Ugandan youths had at least one gambling problem[28] as measured by South Oaks Gambling Scale-Revised for Adolescents.[29] The systematic review echoed a previous review study, which noted the need for policy interventions to limit exposure to and density of outlets, among other suggestions, to reduce gambling harm among young people in SSA.[18] Beyond this systematic review, and in Francophone Africa, Berrada et al. surveyed 200 young male gamblers in Morocco and found that 53% of gamblers were classified as problem gamblers (SOGS 5+).[30]

A body of literature has also explored the prominence of state-sponsored lotteries and horse racing (for French-speaking countries) across the region.[23,31] This literature has noted that these lotteries often emerged in postcolonial states against the backdrop of racist colonial legislation that had previously prohibited or limited 'Africans' from gambling,[32] have provided a source of steady income for states with limited tax bases,[33] but have also become entangled in corrupt political practices.[34] The lotteries literature gives important insight into the gambling policy environments in which contemporary SSA states are situated, but no systematic overview of these environments exists.

Although social sciences and public health research on gambling have responded rapidly to the developments of the last two decades, research on gambling regulation and public health in SSA remains in its infancy. This mirrors wider global concerns that although many countries increasingly recognise the importance of a public health approach to gambling, this often lacks action. As Van Schalkwyk et al. lament, 'no jurisdiction has yet created a gambling regulatory system that explicitly tackles public health concerns and confronts the dependencies and conflicts of interest that undermine the public good while embracing gambling liberalisation'.[35]

In this article, we seek to address this void, as it relates to SSA and to respond to the observation that legislation across the region may not sufficiently control the industry and prevent harm, particularly in a rapidly changing digital age.[4] Specifically, we set out to analyse and compare gambling laws and policies in SSA countries, assess the regulation of gambling in the SSA region, assess the extent of gambling revenues and problems in SSA, identify strengths and weaknesses of gambling policies across SSA and potential areas for policy development.

Methods

We conducted a comparative policy review focused on the regulation of gambling across the SSA region.[36] The review was conducted by obtaining and triangulating data from a desk review of online materials, consultation with regulatory bodies in each territory and the VIXIO Gambling Compliance database.[37]

Desk review

We conducted a desk review of gambling policies across SSA via structured internet searches to characterise the policy environment in each country (see Appendix 1). SSA territories generally publish their laws online, and some regulatory bodies have websites. Wherever available, we sought out these resources to characterise the gambling policy environment in each country. The desk review sought to answer the following 13 questions:

1. What is the legal status of gambling (are there variations by product type)?
2. What legislation is in place and what approach to regulation does it set out?
3. What age restrictions, if any, exist?
4. Does legislation cover online gambling?
5. Does legislation cover marketing/advertising of gambling products?
6. Is there a regulatory body, if so what is it called?
7. Does the regulatory body publish public reports?
8. Do regulatory bodies report on enforcement?
9. Are financial/market data available from regulatory bodies? If so, what do they indicate?
10. Are gambling participation statistics available from regulatory bodies? If so, what do they indicate?
11. Are problem gambling prevalence statistics available from regulatory bodies? If so, what do they indicate?
12. What services for problem gamblers, if any, are publicised by regulatory bodies?
13. Do regulatory bodies use 'responsible gambling' discourse in their reports?

We used a data extraction template in Excel to record summary findings for each of these questions. In all cases, but especially where online laws and regulatory body websites are unavailable, we supplemented our review using Google searches for grey literature using structured terms (see Appendix 1). A snowballing process was applied to identify any potential references of interest

cited in sources that provided answers to our questions and these were also obtained.

Consultation with regulatory bodies and/or experts in each country

In seeking a collaborative and transparent approach, we attempted to contact either the regulatory body or government department responsible for regulation in each country examined.[38] When contact was established, we shared findings from the desk review with regulators or government officials, asked for comments relating to accuracy and invited the submission of any additional resources they deemed instructive, for example, data not in the public domain. Where we had partial information compiled, we shared this with them and requested that they help us fill in missing information. Where we obtained feedback and some information was still unclear; we used phone calls and emails to seek clarification.

The following timeline was applied: first, we emailed regulatory bodies requesting assistance and asking for a reply within 3 weeks; then after 2 weeks from the date of the first email, we sent a reminder email and/or made a telephone call about our request; and finally, after 3 weeks from the date of the first email/contact, we sent another reminder email that offered an additional 2 weeks to respond, together with an explanation that after this period, we will treat their contribution as missing/unavailable.

We attempted to contact 28 regulatory authorities for which contact details were available. However, only eight (28.6%) authorities acknowledged receipt of our email, 14 (50.0%) did not respond to our contacts, and 6 (21.4%) listed inactive email addresses. Of the eight regulators we established contact with, we received feedback from six (21.4%). Among the regulators that responded to us, several thanked the research team for seeking their perspectives and input before publishing findings.

Review of regulatory database

We managed to access country profiles for 29 (59.2%) countries on the VIXIO Gambling Compliance database for SSA territories.[37]The profiles were then triangulated with the data summaries from the desk review and consultation stages by the lead author.

Analysis

We triangulated and summarised data from all three sources in a single Excel spreadsheet. The lead researcher then shared this spreadsheet with each of the authors along with files containing the underpinning evidence to generate the triangulated summary spreadsheet. Each researcher took responsibility for reviewing a subset of countries, cross-checking the summaries with the evidence provided by the lead researcher, making amendments, additions and suggestions before returning these to the lead researcher. The Excel spreadsheet was divided by language (French, English, Spanish and Portuguese) and region (SADC, East Africa, West Africa and Central Africa). The final summary spreadsheet was read by all researchers to check for consistency and accuracy. The summary spreadsheet was then analysed descriptively to construct discrete tabulations of key variables that we present in the findings section.

Results

Legalities of gambling

Of 49 countries within the SSA region, gambling is legally regulated in 41 (83.6%), prohibited in the remaining 7 (14.3%) and is not legislated for in 1 (2.0% see Table S1). One common feature in the seven countries where gambling is illegal is the dominance of the Islamic religion. Islam prohibits the consumption of many products that are not considered 'halal', including gambling.[39,40] We secured legislation and/or equivalent data for all 41 countries where the practice is legal. Of the 41 countries, we obtained contacts (email address and/or phone numbers for regulatory bodies) for 28 (68.3%) countries.

Legal ages of participation in gambling varied between 18 and 25 years. In 37 of 41 (90.2) countries, the legal age for participation is 18 years. In Botswana and Mauritius, the legal age of participation is 21 years, whereas in Uganda, it is 25 years. No data on age restrictions were found for Central African Republic.

Legislation coverage: products, online and advertising

Legislation covering gambling products varied, with many countries having explicit legislation for some products and none for other products (see Table S2). We found explicit legislation for lotteries in 39 of 41 (95.1%) countries, casinos in 39 of 41 (95.1%) and sports betting in 33 of 42 (80.5%). By contrast, we only identified explicit legislation for electronic gaming machines in 13 of 41 (31.7%) countries and for slot machines in 9 of 41 (22.0%). Legislation explicitly addressing online products was identified in 15 of 41 (36.6%) countries and in 18 of 41 (43.9%) for advertising. This finding on online legislation is in line with Gambling Compliance reporting from 2019 according to which only 20% of African jurisdictions regulate online gambling.[41]

Regulating gambling

Of the 41 countries, we found 25 (61.0%) countries that had formed dedicated regulators, and in the remaining 16 (39.0%) countries, regulation was conducted either by a government department or a collaboration between a semi-independent board and government department. Public reporting of regulatory activities was often sporadic and incomplete, with very few regulators publishing regular annual reports. Across the 41 countries, only two (4.9%) published annual reports continuously since formation, and 3 (7.3%) published an incomplete series of reports since formation. In 36 (87.8%) countries, no reports were published. Enforcement activities were documented by all five regulators that published reports (see Data supplement).

Gambling market size, participation and harms

From the reports of the five regulatory bodies for which we accessed reports, limited information was available about market sizes, participation, gambling harms and gambling harm prevention (see Table S4). Market size (gross gambling yield) was reported in Malawi and South Africa, which represent emerging and mature markets, respectively. South Africa's regulatory reporting dates to 2001 include thorough data and has improved in quality over time. Malawi's regulatory reporting, by contrast, only began in 2013. Botswana's regulator was the only one to offer participation statistics, recording that 14,271 used licensed services in the financial year 2019–2020. The rates of harmful gambling, as measured by requests to self-exclude, were reported by Botswana and South Africa, with both signposting harm reduction programmes in their reports. Through consultation with the Malawi Gaming Board, we learnt that they partner with a local mental health service provider to offer free programmes and care to those who approach the Board. This is not advertised in their report, however. Finally, all five regulators made use of 'responsible

gambling' discourse in their reports, often in their mission statements or aims.

Discussion

This review has examined the regulatory measures and structures that are applied to gambling products across SSA. It has demonstrated that regulations exist for all 41 SSA countries in which gambling is legal and that the vast majority require bettors to be at least 18 years. Where gambling was prohibited, this coincided with the dominance of Islamic religious groups. Legislative provision for lottery and casino products was near universal; provision for sports betting was in place for most countries, but with notable gaps; and provision for electronic gaming machine and slots was limited. Legislation addressing online products and marketing varied significantly, with most countries lacking appropriate guidelines for a digital age. The most common organisational approach to regulation was to form a dedicated agency; however, a substantial number of the countries we surveyed nested regulation within a range of government departments. This mirrors the status quo in mature gambling markets such as the United Kingdom, where long-standing calls to recognise gambling as a public health issue have been undermined by a lack of policy coherence and regulatory accountability.[2,42] Public reporting from regulators is also extremely limited both in coverage and content, with only two regulators reporting gross gambling yield, one reporting participation rates, two reporting self-exclusions and three providing information on support services for gamblers in need of help. All the regulatory bodies that produced public reports made use of 'responsible gambling' discourse. This industry-friendly[43] framing also underlies regulatory practice in mature markets such as those of Britain and France.

These concerns about the coherence of regulatory measures are further exacerbated by the lack of transparent public reporting across SSA territories, many of which fail to evidence formal mechanisms of industry monitoring or regulatory enforcement. It is vital that state authorities address this lack of accountability and establish robust preventative controls and reporting measures with the capacity to reduce the risk factors of gambling harm across the continent.

Failure to address the 'upstream' regulatory void could result in a range of 'downstream' implications for public health as commercial gambling markets expand and diversify across the region. This includes a potential increase in the detrimental effects of gambling harms on mental health and well-being and the normalisation of gambling practices among youth demographics.

Particularly urgent, our findings suggest, is the need to address the regulatory void surrounding online and digital forms of gambling, as a primary driver of future industry growth. In heeding lessons from the expansion of commercial tobacco and alcohol industries,[44,45] such measures must be designed and implemented independently of industry actors using evidence-based approaches that suitably acknowledge the technological flexibilisation of gambling practices and the associated potential for harms. Such critical attention to the commercial and technological determinants should extend to assessing the harmful potential of gambling products as part of administering effective prevention-centred controls.

Allied to this, our findings also raise acute concerns about the lack of legislative measures relating to the promotion of gambling products across SSA. Limits on when and where gambling advertising is permitted should be an essential component of any harm prevention policy, particularly as it pertains to children and young people.[46] Furthermore, the content of gambling adverts also demands stringent evaluation to avoid misleading messaging that overstates the probability of winning and/or depicts gambling in ways that glamorise or normalise its appeal. Evidence from other territories suggests that prevention strategies controls are vital to denormalising and counteracting industry messages depicting gambling not only as a fun, risk-free leisure form but as a 'quick fix' route to wealth creation, particularly in contexts of labour precarity and youth un(der)employment.[47,48]

Contrary to the ubiquitous use of 'responsible gambling' discourse by those regulators that published public reports, it is imperative that state authorities move beyond a policy focus on the diagnosis and containment of 'problem gambling', which tends to stigmatise and shame individuals for a lack of self-control,[49] to rigorously appraise the environmental and structural drivers of gambling harms.[50] This systematic policy shift, from individual responsibility to commercial accountability, is fundamental to ensuring appropriate safeguards for those experiencing gambling harms.

Overall, given the mounting evidential basis for a public health approach to regulating gambling in the Global North,[2,42] and the emerging research from SSA, our findings underline the potential for an increase in gambling-related harms as the industry intensifies its activities across the continent. Of foremost importance, then, is the need for a collective reckoning at the national and regional levels with the regulatory gaps that, if left unchecked, will enable the acceleration of commercial gambling expansion, and further exacerbate existing health inequalities across SSA. This will require concerted effort from civil society, policy actors and service providers to establish the expansion of the gambling industry in the region as a pressing social and political concern at a time when governments across SSA face multiple catastrophic challenges, for example, climate change, food precarity, COVID-19–related economic fallout.

Vital consideration must also be given to socio-economic and cultural factors, including the potential effects of high rates of labour precarity and unemployment, including youth unemployment, on the risk and appeal of industry discourses promoting gambling as a source of income and wealth. Further research is merited in a number of areas: including the relationship between gender and gambling, including the extent to which traditional norms impact on consumption habits and domestic attitudes towards gambling; the salience of religious, spiritual and folk religion practices in the uptake of gambling by particular groups; and the role of sport, particularly football, as a cultural vehicle closely aligned with the promotion and advertising of gambling products.

Finally, the policy review also revealed that the expansion of commercial gambling to African countries often followed a neocolonial logic in that we uncovered French products, such as horse racing, being pushed to the French-speaking market[23] and English products, such as English football, was pushed to English-speaking markets.[9] Similarly, the regulatory choices also appear to be heavily influenced by former colonial relations. For example, the legislations in the French-speaking African countries had taken practices from France, whereas the English-speaking African countries modelled their legislation practices to those of the United Kingdom. It was the same case for the Portuguese-speaking African countries. The fact that both commercial and regulatory practice so closely mirror the former colonial relationships ultimately emphasises the enduring hegemonic power of neo-colonialism. In turn, this potentially has huge implications for how gambling is framed and dealt with across SSA, going forward.

As a point of departure for reform, our findings also shed light on how particular territories could lead to policy sharing on harm reduction strategies. Current examples of 'best practice' include increasing age limits on participation (in Uganda, the legal age is 25

years); stringent restrictions of advertising (as in Mauritius); remuneration for counselling services (as in Malawi); and the endorsement of regular and transparent reporting mechanisms.

Finally, several study limitations should be noted. First, this desk-based review study was unable to assess the veracity of reporting mechanisms nor the degree of enactment and enforcement of regulatory policies on gambling. Addressing this gap should be a priority for further research. Second, while the project team was expanded to add linguistic diversity, the project was conducted by a majority of Anglophone speakers. Third, owing to logistical realities, the project team did not have the capacity to visit regulators in person but acknowledge that this may have provided a more complete data set and ameliorated the low response rate from regulators in a high number of SSA territories.

These limitations notwithstanding, the study is, to our knowledge, the first comprehensive mapping of regulatory and legislative policy on gambling across SSA territories, using an innovative participatory approach that actively engaged with state authorities and regulators and triangulated multiple data sources that were reviewed and coded across the project team.

Author statements

Ethical approval

Ethical approval was obtained from the Research Ethics Approval Committee for Health (REACH) at University of Bath (Ref number: EP 20/21 009).

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Competing interests

None declared.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.07.018.

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Review Paper

Relationship between formaldehyde exposure, respiratory irritant effects and cancers: a review of reviews

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ABSTRACT

Objectives: Formaldehyde is an organic compound used in the production of resins, paper, wood plywood, solvents and cleaning products. Formaldehyde is also present when tobacco is smoked. Formaldehyde has been defined as an irritant and is classified as a human carcinogen by the International Agency for Research on Cancer. The purpose of this study was to demonstrate the following two distinct correlations: (1) the association between formaldehyde exposure and development of irritant diseases affecting the respiratory tract, mainly asthma; and (2) the association between formaldehyde exposure and development of neoplastic diseases.

Study design: This was an umbrella review.

Methods: A search was conducted in the three main electronic databases of scientific literature: PubMed, Scopus and Web of Science. The search included systematic reviews and meta-analyses published in the previous 10 years. Initially, titles and abstracts of retrieved articles were evaluated, then full-text assessments of selected articles took place. Data extraction and quality assessment were performed according to Assessing the Methodological Quality of Systematic Reviews (AMSTAR) score.

Results: A total of 630 articles were initially collected. Nine articles concerning the association between formaldehyde exposure and asthma were included in the present review, and the majority of these reported good association. In addition, 27 articles investigating the association between formaldehyde exposure and neoplastic diseases were included in the review. These studies showed that nasopharyngeal cancer and leukaemia were the most represented neoplastic diseases; however, only a weak association was reported between formaldehyde exposure and cancer.

Conclusions: Although the studies included in this review did not show a strong association between exposure to formaldehyde and irritant or neoplastic diseases, the World Health Organisation recommends that levels of formaldehyde do not exceed the threshold value of 0.1 mg/m^3 (0.08 ppm) for a period of 30 min. It is recommended that preventive measures, such as ventilation in workplaces with high exposure to formaldehyde and environmental monitoring of formaldehyde concentrations, are implemented.

Introduction

Formaldehyde is an organic compound and is the simplest form of aldehyde. At room temperature, it is a colourless gas with a pungent odour. It is one of the most common indoor pollutants and is the main precursor of many other chemical compounds, especially polymers. Formaldehyde is used in the production of formaldehyde resins, particle board, paper, plywood and urea-formaldehyde foam.[1] The main internal sources of formaldehyde are pressed wood products, insulation materials, paints, varnishes, household cleaning products and cigarettes.[2] Formaldehyde is also present as an antimicrobial agent in many cosmetic products.[3]

Since the early 1980s, the National Institute for Occupational Safety and Health has recommended that formaldehyde should be considered a potential occupational carcinogen and that appropriate measures should be taken to reduce workers' exposure.[4] The toxicology and epidemiology of formaldehyde were discussed at the second International Formaldehyde Science Conference in

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Madrid, Spain, 19–20 April 2012. It was noted that a substantial amount of new scientific data has appeared since the first conference in 2007.[5]

According to the Scientific Committee on Occupational Exposure Limits, formaldehyde is considered a 'genotoxic carcinogen, for which a practical threshold is supported' and an occupational exposure limit of 0.2 ppm has been recommended.[6] However, in accordance with recent epidemiological results, the World Health Organisation (WHO) recommends a formaldehyde threshold value of 0.08 ppm, which is preventative for carcinogenic effects.[7]

Absorption, distribution, metabolism and elimination

Because of the high water solubility and reactivity of formaldehyde, when dispersed in the air, it is primarily absorbed (90%) in the upper airways.[8] In tissues, formaldehyde reacts with water and forms methylene glycol (methanediol), which represents over 99.9% of the total formaldehyde in the aqueous phase.[9] Furthermore, formaldehyde reacts with DNA, RNA and proteins forming covalent bonds. Formaldehyde is also an endogenous metabolite, and its concentration in the blood is approximately 2–3 mg/L. The half-life of formaldehyde in the blood is 1–1.5 min.[8,10] It is interesting to note that endogenous formaldehyde is produced by numerous biochemical pathways that are fundamental to life, it can cross-link both DNA and proteins, and it can be carcinogenic according to Dingler et al.[11] and Pontel et al.[12] Moreover, Umansky et al. identified formaldehyde as an endogenous molecule that can cause oxidative stress and cytotoxicity.[13]

An important scientific advancement has been the ability to differentiate between exogenous DNA-damaging and endogenous (normal) forms of formaldehyde. Following inhalation of isotope-labelled formaldehyde (13CD2O), DNA-13CD2-DNA cross-links were noted in the nasal tissue. In contrast, endogenous formaldehyde was detected in all tissues.[14]

In addition, substantial variation in individual responses to formaldehyde in humans has been reported. Tan et al. demonstrated that in cells bearing BRCA2 heterozygous mutations, formaldehyde was capable of stalling and destabilising DNA replication forks, resulting in structural chromosomal aberrations.[15]

Related diseases

The effects of formaldehyde can be divided according to the concentration of exposure. At the lowest concentrations, there is the perception of smell, followed by sensory irritation of the eyes, nose and throat, the upper respiratory tract, up to asthmatic symptoms, such as dyspnoea and wheezing.[16] On the other hand, in 2000, the WHO air quality guidelines for Europe underlined that there was epidemiological evidence for associations between relatively high occupational exposure to formaldehyde and both nasopharyngeal and sinonasal cancers.[7] Consequently, it is important to determine the concentration of formaldehyde that is associated with the onset of sensory irritation symptoms, rather than the simple detection of smell.

It is important to emphasise that sensory irritation and olfactory perception are two different and distinct phenomena: smell is the sensation carried by the olfactory nerve, whereas sensory irritation involves the stimulation of the trigeminal nerve. The latter response of the organism is however considered a physiological and non-toxic event, as it does not occur in conjunction with tissue damage or cellular lesions.[17–20] Formaldehyde-induced cytotoxicity does not occur at concentrations above those necessary to activate the sensory irritation system (i.e. $\geq$2 ppm).[21] A guidance document[22] notes that the odour threshold for formaldehyde is 0.8 ppm but also states that people with sensitive noses can detect formaldehyde at levels as low as 0.1 ppm. Another study by Noisel et al.[23] reported an odour detection level of 0.75 ppm, with a minimum irritant level of 1.0 ppm, whereas the US Environmental Protection Agency (EPA)[24] reported an odour detection level of 0.5 ppm (consistent with the Agency for Toxic Substances and Disease Registry), with a minimum irritation level of 1.5 ppm.

For formaldehyde-induced sensory irritation, there are essentially no significant differences between short- and long-term exposure.[25–27] The Organization for Economic Co-operation and Development Screening Information Data Set[28] reported, 'Studies in the literature have reported a variety of responses induced by exposure to gaseous formaldehyde, which generally begins in 0.3–0.5 ppm range for eye irritation. However, the severity of the response at these levels is generally mild and only a small portion of the population can respond.'

The purpose of this study was to demonstrate the following two distinct correlations: (1) the association between formaldehyde exposure and development of irritant diseases affecting the respiratory tract, mainly asthma; and (2) the association between formaldehyde exposure and development of neoplastic diseases.

Methods

Study design

This study was an umbrella review. A detailed protocol for the review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO CRD42021232563).[29] The Preferred Reporting Items for Systematic reviews and Meta-Analyses statement and the guidelines developed by Aromataris et al. were followed to perform an umbrella review.[30]

Search strategy

The identification of relevant studies for this review was obtained by searching PubMed, Scopus and Web of Science electronic databases of scientific literature. The search strings used were as follows:

'(Formaldehyde) AND (Cancer OR tumor OR neoplasm OR malign)'; and '(Formaldehyde) AND (asthma OR allergy OR reactive airway disease)'. The search was performed without language restrictions for articles published in the previous 10 years.

Study selection

Identified articles were uploaded on the JabRef 5.2 software, and duplicates were removed. The selection process was divided into two phases. In the first phase, titles and abstracts of the articles were evaluated; in the second phase, articles selected after the first phase assessment underwent full-text evaluation to deem whether they met the inclusion criteria.

Inclusion criteria

Selected studies consisted of systematic reviews and meta-analyses. Primary studies, narrative reviews and all studies that did not have a systematic review approach were excluded. Studies published within the last 10 years were selected.

The inclusion criteria are described according to the Population, Intervention, Comparison and Outcomes (PICOS) approach, as follows.

- Population: Human population exposed to formaldehyde;
- Phenomenon of interest: (1) Association between formaldehyde exposure and reactive airway diseases; (2) Association between formaldehyde exposure and Cancer;
- Comparators: Nobody;
- Results: All;
- Time window: Last 10 years;
- Type of study: Systematic reviews and meta-analyses.

Data extraction and quality assessment

Data extracted from the articles included year of publication, type of study, characteristics of the population under study and effects of exposure to formaldehyde, such as cancer and respiratory diseases. A quality assessment was performed using Assessing the Methodological Quality of Systematic Reviews (AMSTAR) 2 for systematic reviews and meta-analyses. The overall final quality of each systematic review/meta-analysis was rated as high, low or critically low.

Results

Initially, 630 articles were retrieved from the literature search of the three electronic databases (PubMed, Scopus and Web of Science).

Formaldehyde exposure and asthma

In total, 153 articles investigated the association between formaldehyde exposure and asthma. After duplicate removal, 95 articles remained. In the first phase, titles and abstracts of the articles were evaluated, which led to the removal of a further 73 articles. The remaining 22 articles underwent a second phase evaluation, where careful reading of the full text took place. Finally, nine articles were included in the review (see Fig. 1).

Characteristics of the asthma studies

The characteristics of the selected systematic reviews and meta-analyses investigating the association between formaldehyde exposure and asthma are shown in Table 1.

Children were the primary population group investigated in the selected studies, as the impact of formaldehyde exposure on asthma appears to be greater in children. The differences in outcomes of formaldehyde exposure on asthma between adults and children can be explained as follows: first, children spend more time indoors than adults, leading to a greater indoor formaldehyde exposure, causing a more noticeable asthmatic effect[31]; second, children are generally more susceptible to air pollution than adults because of a faster respiratory rate and a respiratory volume that is 50% higher than adults[32]; and third, due to the physiologically immature immune system, children may be more susceptible to the negative effects of formaldehyde.

According to Yu et al.,[33] children exposed to low formaldehyde concentrations ($\leq$22.5 $\mu g/m^3$) had a significantly increased risk of asthma, and each 10 $\mu g/m^3$ increase in exposure to formaldehyde induced a 10% increase in the risk of asthma in children (odds ratio [OR] 1.10; 95% confidence interval [CI] 1.00–1.21). Formaldehyde exposure may also be associated with an increased risk of asthma among adults if exposed at high doses (formaldehyde > 22.5 $\mu g/m^3$; OR 1.81; 95% CI 1.18–2.78).

According to the article by Yao et al.,[34] the weighted mean difference in formaldehyde concentration is 0.021 (95% CI 0.009–0.033); thus, the mean formaldehyde concentration in the group of people with asthma is higher than the mean formaldehyde concentration in the control group in the environment. These results confirm the hypothesis that exposure to formaldehyde is related to the onset of asthma.

Vardoulakis et al.[35] underline that the concentration of indoor formaldehyde varies in a range of 7.5–134 g/m^3, which includes values of formaldehyde that could induce irritant diseases such as asthma. Nielsen et al.[8] collected the results of many studies that established an association, albeit weak, between exposure to formaldehyde and asthma and reported an OR of 1.31 (95% CI 1.10–1.57).

The study by McGwin et al.[36] differs from the other selected studies, as it provides a specific analysis of data describing the correlation between formaldehyde exposure and asthma. McGwin et al. calculated the OR in random models and in fixed effects models; the first OR is 1.17 (95% CI 1.01–1.369), and the second OR is 1.03 (95% CI 1.02–1.04).

Finally, in the study carried out by Golden,[9] the association between asthma and formaldehyde exposure is represented by an OR of 1.4 (95% CI 0.98–2.0).

Quality assessment of the included asthma studies

The methodological quality of the included studies that analysed the association between formaldehyde exposure and asthma is shown in Table S1 in the supplementary material. The methodological quality assessment according to AMSTAR highlights that 45% of the articles had a high total score, thus reaching a good methodological quality. However, the remaining 55% had weak methodological quality, and 22% of these were defined as critically low.

Formaldehyde exposure and cancer

The database search identified 477 articles that analysed the association between formaldehyde exposure and cancer. After duplicate removal, 213 articles remained. In the first phase, titles and abstracts of the articles were evaluated, which led to the removal of a further 152 articles. The remaining 61 articles underwent a second phase evaluation, where careful reading of the full text took place. Finally, 27 articles were included in the review (see Fig. 2).

Characteristics of the included cancer studies

The articles included in this review analysed the association between formaldehyde exposure and neoplastic diseases, reporting the evidence and studying the data that either confirm or reject this hypothesis. The characteristics of the included systematic reviews and meta-analyses are shown in Table 2.

Formaldehyde and nasopharyngeal cancer

The study by Nielsen et al.[8] explored the association between formaldehyde exposure and nasopharyngeal cancer and detected a higher incidence of neoplasia among workers exposed to a formaldehyde concentration above four ppm. These results are in line with the WHO guidelines that indicate the average level of exposure to formaldehyde must be less than one ppm.

Another study by Nielsen et al.[37] reported epidemiological studies that analysed the association between formaldehyde exposure and nasopharyngeal cancer, indicating that the WHO guidelines (<0.1 mg/m^3) are highly precautionary due to a non-linear exposure–response and the epidemiological effects

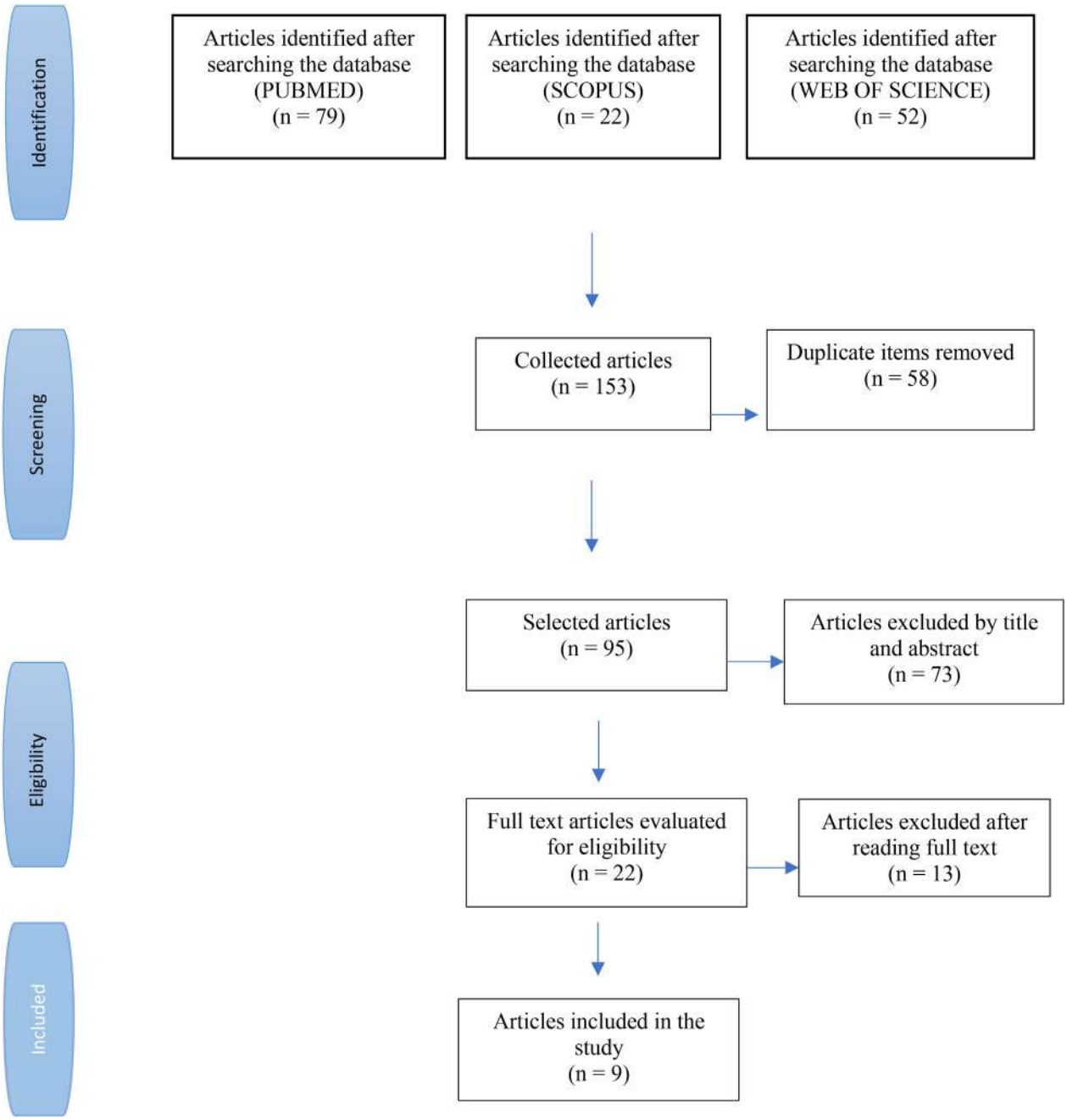

Fig. 1. PRISMA flow chart – association between formaldehyde exposure and asthma.

following exposure to formaldehyde concentrations, which were far higher than those indicated by the WHO guidelines.

The reviews carried out by Charbotel et al.[38] and Binazzi et al.[39] investigated the association of formaldehyde and cancer, demonstrating a weak association with nasopharyngeal cancer (OR 1.22; 95% CI 1.00–1.50) and cancer of the nasal and sinus cavity (relative risk [RR] 1.68; 95% CI 1.37–2.06), respectively.

Bachand et al.[40] included 35 primary studies (cohort and case–control studies) and indicated a lack of association between exposure to formaldehyde and neoplastic diseases, such as nasopharyngeal cancer (RR 0.72; 95% CI 0.40–1.28).

On the other hand, another meta-analysis analysed studies that supported the association between formaldehyde exposure and nasopharyngeal cancer (OR 2.7; 95% CI 1.2–6.0); however, the study did highlight that the risk increases with a longer duration of exposure to formaldehyde.[41]

Formaldehyde and leukaemia/lymphoma

One study, by Rhomberg et al.,[42] states that researchers report the lack of possible association between formaldehyde exposure and leukaemia. This study states that there is a lack of scientific evidence about toxic-kinetic and mechanistic biological plausibility to prove an association between formaldehyde exposure and cancer.

The review carried out by Polychronakis et al.[43] investigates the association between formaldehyde exposure and leukaemia, and despite showing an RR of 1.42 (95% CI 0.92–2.18) with formaldehyde exposure >4 ppm and finding greater genetic aberrations

Table 1
Characteristics of selected studies investigating the formaldehyde-asthma association.

Author	Year of publication	Number of studies/patients	Types of studies	Exposed occupational group	Results	AMSTAR quality judgement
Mc Gwin et al.[36]	2010	10/6387	Cohort studies; case–control studies; cross-sectional studies	Children at home, at school and outdoors	Good association OR 1.17; 95% CI 1.01–1.36	High (7)
Wolkoff et al.[55]	2010	12/4443	Case–control studies; cross-sectional studies	- Workers exposed to wood and resin - Children at home exposed to solvents, household products	Good association OR 1.40; 95% CI 0.98–2.00	Low (5)
Golden[9]	2014	13/not reported	Cohort studies; case–control studies	- industrial workers - Children at home	Good association OR 1.4; 95% CI 0.98–2.0	Critically low (2)
Nielsen et al.[8]	2013	12/657	Cohort studies; case–control studies; cross-sectional studies	- Pathologists - Woodworkers - Anatomists - Laboratory workers	Weak association OR 1.31; 95% CI 1.10–1.57	Critically low (2)
Nurmatov et al.[57]	2015	14/not reported	Cohort studies; case–control studies; cross-sectional studies	- Laboratory workers - Children at home	Good association From OR 1.58; 95% CI 1.04–1.83 to OR 2.51; 95% CI 1.4–3.6	High (7)
Tagiyeva et al.[56]	2014	30/not reported	Interventions; cohort studies; case–control studies; cross-sectional studies	- Woodworkers, exposed to cosmetics, textiles, household products - Children indoors	Good association Children: OR 4.3; 95% CI 2.1–8.8 Adults: OR 2.6; 95% CI 1.8–3.6	Low (5)
Yao et al.[34]	2015	6/356	Cohort studies; case–control studies	- Children outdoors	Good association WMD 0.021; 95% CI 0.009–0.033	High (9)
Yu et al.[33]	2020	13/10,458	Cohort studies; case–control studies; cross-sectional studies	- Adults (industrial workers and exposure at home) - Children at home and at school	Children: OR 1.10; 95% CI 1.00–1.21 Adults: OR 1.33; 95% CI 1.18–2.78	High (9)
Vardoulakis et al.[35]	2020	33/not reported	Case–control studies; cross-sectional studies	- Workers of wood and house products	Good association OR 1.37; 95% CI 1.01–1.89	Low (5)

CI, confidence interval; OR, odds ratio; WMD, weighted mean difference.

among workers exposed to formaldehyde than those not exposed, the study reports a consistent scepticism towards the association between formaldehyde exposure and leukaemia. These results are supported by the inconsistency of the epidemiological data and a lack of plausibility of the formaldehyde action model in leukaemia.

Mundt et al.[44] analysed the frequency of aneuploidy among workers exposed to formaldehyde in a resin factory. The results showed the absence of association between the exposure to formaldehyde and myeloid leukaemia (of which aneuploidy is considered a risk indicator).

A meta-analysis focuses on chromosomal studies of samples from workers exposed and not exposed to formaldehyde. This study deduced that the observed chromosomal aberrations, namely, monosomy 7 and trisomy 8, attributable to high exposure to formaldehyde, could have arisen during *in vitro* culture and not *in vivo*. Therefore, the results of these data, in combination with toxicological and mechanistic studies, do not support the causal association between exposure to formaldehyde and myeloid or lymphoid neoplasms.[45]

However, another study investigated the frequency of lymphocyte micronuclei in formaldehyde-exposed vs unexposed groups (case–control study). The results indicated a two-fold increase in lymphocyte frequency in those exposed compared with the control cases ($P < 0.0001$). Furthermore, the increase in the frequency of micronucleus (MN) in lymphocytes in exposed individuals compared with non-exposed individuals was strongly associated with the duration of exposure to formaldehyde, suggesting the need to better understand the potential for genomic instability induced by chronic formaldehyde exposure.[46]

A systematic review carried out by Awan et al.,[41] investigating industrial cohort studies and professional cohort studies on the association between formaldehyde exposure and lymphohematopoietic neoplasms, showed inconsistent results with RR values close to zero (RR 1.78; 95% CI 0.87–3.64 for myeloid leukaemia; RR 1.42; 95% CI 0.92–2.18 for non-myeloid leukaemia).[41]

The study by Charbotel et al.[38] considers the association of formaldehyde exposure and leukaemia and identifies a significant association with chronic and acute myeloid leukaemia (RR 2.47; 95% CI 1.42–4.27).

The meta-analysis by Catalani et al.[48] investigated 12 reports of workers exposed to formaldehyde with the aim of finding a connection with the onset of Hodgkin's lymphoma; however, the results, with an RR of 0.93 (95% CI 0.83–1.04) do not support an association. Another study performed in 2010 by Nielsen et al.,[49] collected 35 primary studies (cohort and case–control studies) and highlighted a lack of association between formaldehyde exposure and leukaemia (RR 1.05; 95% CI 0.93–1.20).

Allegra et al.[50] analysed results from 81 primary studies and reported a lack of evidence to support the hypothesis that formaldehyde is a cause of acute myeloid leukaemia.

In the study by Albertini et al.,[51] DNA damage in the lymphocytes of workers exposed to formaldehyde was measured; however, the results of this investigation showed that changes in human bone marrow or hematopoietic cells had confounding exposures, and *in vivo* and *in vitro* events could not be distinguished. Therefore, genetic changes reported in the analysed studies do not provide convincing data in support of the classification of formaldehyde as a human leukemogen.

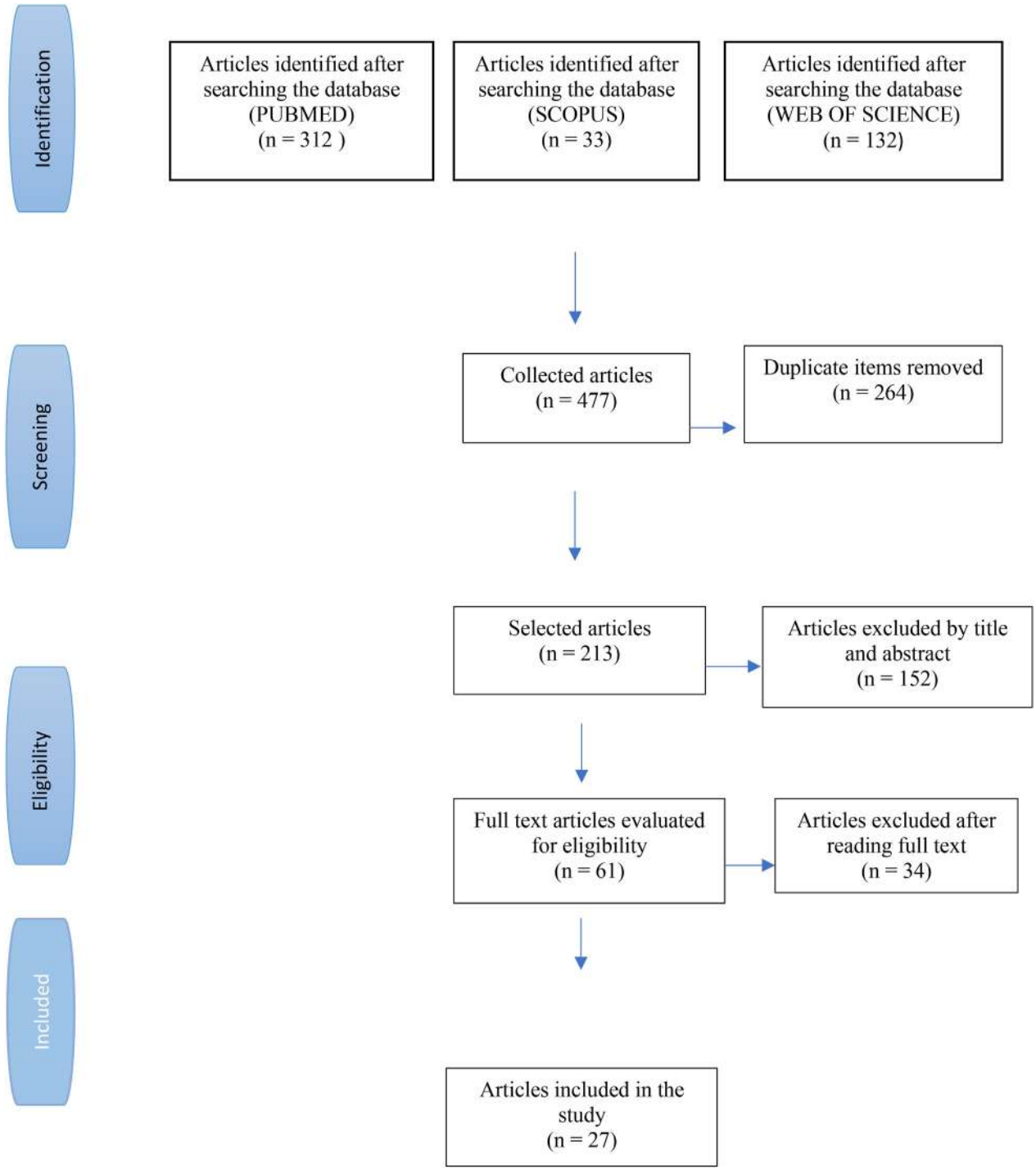

Fig. 2. PRISMA flow chart – association between formaldehyde exposure and cancer.

The meta-analysis by Shallis et al.[52] considers seven different prospective and retrospective cohort studies that present conflicting results; some report a weak association (not statistically significant) between formaldehyde exposure and leukaemia with an RR of 1.78 (95% CI 0.87–3.64), whereas others support a strong association (statistically significant) between formaldehyde exposure and myeloid leukaemia with an OR of 13.6 (95% CI 1.6–119.7).

Formaldehyde and other cancers

The study by Paget-Bailly et al.[53] evaluated case–control studies reporting data that do not support the hypothesis of an association between laryngeal cancer and formaldehyde exposure with an RR of 1.13 (95% CI 0.98–1.31).

Kwak et al.[54] made a quantitative assessment of the data from a review of 30 articles and found that there was no significant increase in lung cancer risk with formaldehyde exposure.

Table 2
Characteristics of selected studies investigating the formaldehyde-cancer association.

Author	Year of publication	Cancer type	Number of studies/ participants	Type of studies	Occupational group	Results	AMSTAR quality judgement
Bachand et al.[40]	2010	NPC, leukaemia	18 for NPC 17 for leukaemia/ 161,718	Cohort studies; case −control studies	- Embalmers - Pathologists - Paper workers	Weak association OR 1.10; 95% CI 0.80−1.50	High (9)
Nielsen et al.[49]	2010	NPC, leukaemia	12 for NPC 18 for leukaemia/657		- Pathologists - Anatomists - Embalmers	Weak association r 1.33; 95% CI 0.69−2.56	Low (5)
Golden[9]	2011	NPC, leukaemia	14/not reported	Cohort studies; case −control studies	- Industry workers	Weak association r 0.72; 95% CI 0.40−1.28	Critically low (2)
Rhomberg et al.[42]	2011	Leukaemia	53/458,782	Cohort studies; case −control studies	- Pathologists - Medical laboratory technicians - Embalmers	Weak association OR 1.20; 95% CI 0.60−2.30	High (8)
Checkoway et al.[47]	2012	Leukaemia	37/293,060	Industrial cohort studies; professional cohort studies; population-based case −control studies	- Pathologists - Anatomists - Woodworkers - Chemical industry workers	Weak association Myeloid leukaemia: r 1.78; 95% CI 0.87−3.64 Other (non-myeloid) leukaemia: r 1.42; 95% CI 0.92−2.18	High (7)
Paget-Bailly et al.[53]	2012	Cancer of the larynx	11/not reported	Cohort studies; case −control studies	- Metal industry workers	Weak association OR 1.3; 95% CI 0.5−3.3	High (10)
Gentry et al.[45]	2013	Leukaemia	1/94	Meta-analysis	- Industry workers	Weak correlation $P = 0.10$	Low (4)
Nielsen et al.[8]	2013	NPC	8/657	Cohort studies; case −control studies	- Pathologists - Woodworkers - Anatomists - Laboratory workers	Weak association OR 1.13; 95% CI 0.98−1.31	Critically low (2)
Polychronakis et al.[43]	2013	Leukaemia	4/not reported	Cohort studies; case −control studies; epidemiological or molecular study; letter to the editor	- Embalmers	Weak association r 1.37; 95% CI 1.03−1.81	High (7)
Bayer et al.[63]	2014	Cancer of the larynx	21/17,722	Cohort studies; case −control studies	- Wood and paper workers	Weak association OR 1.20; 95% CI: 1.02−1.40	High (9)
Charbotel et al.[38]	2014	- Nasal-pharyngeal cancer - Cancer of the nasal and paranasal cavity - Acute and chronic myeloid leukaemia - Salivary gland cancer	6/not reported	Meta-analysis; Case−control studies	- Woodworkers	Weak association for cancer of the nasal and paranasal cavity: OR 1.22; 95% CI 1.00 −1.50 and OR 9.5; 95% CI 2.62−34.20 Good association for leukaemia: OR 2.47; 95% CI 1.42−4.27 Good association for salivary gland cancer: OR 1.61; 95% CI: 1.30−2.00	Low (4)
Fenech et al.[46]	2015	NPC	17/952	Cohort studies; case −control studies	- Anatomists - Workers exposed to FA from resins and wood manufactures	Good correlation r 0.779; $P < 0.0001$	High (8)
Binazzi et al.[39]	2015	Sinus cancer	7/not reported	Cohort studies; case −control studies	- Woodworkers	Good association r 1.75; 95% CI 1.21−2.43	High (9)
Albertini et al.[51]	2016	Leukaemia/lymphoma	53/not reported	Cohort studies; case −control studies	- Pathologists - Anatomists - Woodworkers - Chemical industry workers	Good association r 1.31; 95% CI 1.07−1.60	Low (4)
Chappell et al.[60]	2016	NPC, leukaemia	4/not reported	Not specified	Industry workers		Low (5)

						Good correlation r 0.384; $P = 0.001$	
D'Ettorre et al.[58]	2016	NPC, myeloid leukaemia	31/not reported	Cohort studies; case−control studies	Pathological anatomy workers	Good correlation $P < 0.05$	Low (5)
Gurbuz et al.[59]	2016	NPC	27/not reported	Cohort studies; case−control studies	Laboratory workers	Good correlation $P < 0.05$	Low (4)
Nielsen et al.[37]	2017	NPC, leukaemia	8/657	Cohort studies; case−control studies	- Pathologists - Woodworkers	Good association for NPC: r 7.7; 95% CI 0.9−62 Weak association for leukaemia: r 1.15; 95% CI 0.97−1.36	Critically low (3)
Menicagli et al.[62]	2017	NPC	Not specified	Cohort studies; narrative reviews	Rubber and wood workers	Good correlation $P < 0.05$	Critically low (1)
Mundt et al.[44]	2017	Myeloid leukaemia	1/not reported	Cross-sectional studies	Industry workers	Weak association OR 0.80; 95% CI 0.70−0.92	Low (5)
Awan et al.[41]	2018	NPC, hypopharyngeal cancer	2/not reported	Case−control studies	Wood and solvent workers	Good association OR 2.7; 95% CI 1.2−6.0	High (8)
Allegra et al.[50]	2019	Acute myeloid leukaemia	81/not reported	Cohort studies; epidemiological molecular studies; literature review	Laboratory personnel	Good association OR 2.45; 95% CI 1.32−4.52	Low (5)
Beigzadeh et al.[61]	2019	NPC	7/13,296	Cohort studies; case−control studies	woodworkers	Good association OR 1.5; 95% CI 1.09−2.07	High (9)
Catalani et al.[48]	2019	Non-Hodgkin's lymphoma	12/318	Cohort studies	- Embalmers - Anatomists - Wood industry workers - Laminated plastic workers	Weak association r 0.93; 95% CI 0.83−1.04	High (9)
Kwak et al.[54]	2020	Lung cancer	31/1,339,927	Cohort studies; case−control studies; PMR/PIR studies	- Medical technicians - Embalmers - Chemists	Weak association OR 1.04; 95% CI 0.97−1.12	High (9)
Shallis et al.[52]	2020	Acute myeloid leukaemia	7/39,633	Retrospective cohort studies; prospective cohort studies; meta-analysis, case−control studies	- Embalmers - Funeral home workers - Anatomists - Pathologists	Weak association r 1.42; 95% CI 0.92−2.18	High (7)
Vardoulakis et al.[35]	2020	Nasopharyngeal cancer	33/not reported	case−control studies; cross-sectional studies	Woodworkers and household products	Good association OR 1.37; 95% CI1.01−1.89	Low (5)

CI, confidence interval; FA, formaldheyde; NPC, nasopharyngeal cancer; OR, odds ratio; WMD, weighted mean difference.

The study by Charbotel et al.[38] analyses the association of formaldehyde with multiple types of rare neoplasms; among others, it shows a weak association with salivary gland cancer (OR 1.6; 95% CI 1.30–2.00).

Quality assessment of the included cancer studies

The methodological quality of the included reviews that analysed the association between formaldehyde exposure and cancer, performed according to AMSTAR scale, is shown in Supplementary Table S2. In total, 48% of the articles reported good scores for methodological quality; however, 37% had weak methodological quality, and 15% had a critically low methodological quality.

Summary of the results

Table 3 shows a summary of the associations found between formaldehyde exposure and different diseases.

Almost all the articles (8 of 9) demonstrate a positive association between formaldehyde exposure and asthma[9,33–36,55–57]; only the study by Nielsen et al.[8] showed a negative association between exposure to formaldehyde and asthma.

In total, 64% of the reviews showed evidence for the association between formaldehyde exposure and nasopharyngeal cancer, whereas only 33% supported the association between formaldehyde exposure and leukaemia/lymphoma. Among these articles, the association between exposure to formaldehyde and myeloid leukaemia was discussed.[43,44,50,52,58]

Discussion

The purpose of this study was to demonstrate the following two distinct correlations: (1) the association between formaldehyde exposure and development of irritant diseases affecting the respiratory tract, mainly asthma; and (2) the association between formaldehyde exposure and development of neoplastic diseases.

Some articles included in this review highlighted that children were most significantly impacted by formaldehyde exposure. Some articles[8,9,33,35,55,56] are in agreement with the WHO guidelines that state the concentration of formaldehyde must not exceed 0.1 mg/m^3 (0.08 ppm) for a period of 30 min.

From the selected cancer articles, the most common neoplasms associated with formaldehyde exposure were shown to be nasopharyngeal cancer and leukaemia[8,9,35,37,40,42–52,58–63] A small number of articles considered the association between exposure to formaldehyde and other types of cancers; Paget-Bailly et al.[53] and Bayer et al.[63] investigated the risk of laryngeal cancer among formaldehyde-exposed workers. In addition, the meta-analysis by Kwak et al.[54] analysed the risk of lung cancer following formaldehyde exposure in professional employment. Another study also mentioned rare neoplasms, such as salivary gland cancer.[38] Finally, in the systematic review by Binazzi et al.,[39] the association between cancer of the nasal cavity and paranasal sinuses in workers exposed to formaldehyde was studied.

Table 3
Number of reviews describing an association between formaldehyde exposure and different diseases.

Type of disease	Association	
	No	Yes
Asthma	1	8
Nasopharyngeal cancer	5	9
Leukaemia/lymphoma	10	5
Larynx cancer	2	0
Salivary gland cancer	0	1
Sinus cancer	0	1
Lung cancer	1	0

The selected articles show that the workers who are most at risk of exposure to formaldehyde include laboratory workers (anatomists, pathologists, and chemists), embalmers and those who work in the production of plywood and resins, with wood dust and solvents.[8,39–42,46–49,52,54,58,59,61,63]

The WHO guideline threshold values of formaldehyde exposure (i.e. 0.1 mg/m^3 [0.08 ppm] for a period of 30 min) were taken as referral values in many of the included studies.[8,9,35,37,49,59]

Future research should include surveillance studies that are capable of adequately measuring the level of formaldehyde exposure and the occurrence of diseases in cohort or case–control studies.

The main implications for public health practice and policy, as well as for health and safety or occupational health, are related to the implementation of the WHO guidelines threshold values of formaldehyde exposure (i.e. 0.1 mg/m^3 [0.08 ppm] for a period of 30 min). If this concentration is exceeded in occupational/workplace settings, strategies must be implemented to reduce exposure, such as reducing the number of workers exposed, reducing the duration of exposure, better collection and ventilation systems, and use of appropriate personal protective equipment.

Limitations and strengths

This review had several limitations that should be acknowledged. The study populations in the analysed reviews are very specific (i.e. school-aged individuals with regard to the association between formaldehyde exposure and asthma; and professional workers with regard to the association between formaldehyde exposure and cancer). Only articles published in the previous 10 years were included, thus excluding studies published before 2010. In the meta-analyses included in this review, the authors underline that among the primary studies analysed, there were, in some cases, a high risk of bias. Moreover, it should be noted that the studies included in the systematic reviews and meta-analyses were performed with relatively small groups of people, and it was difficult to retrieve any information about ethnicity or gender.

However, this review also has several strengths. The results provide a global view of the association between exposure to formaldehyde and the potential associated pathologies. In addition, a dual analysis was performed, assessing how the exposure to formaldehyde could impact individuals by causing both irritant and neoplastic pathologies. The review also included an assessment of the AMSTAR methodological quality.

Conclusions

The present review showed a positive association between exposure to formaldehyde and irritant diseases, such as asthma, as seen in 89% of the articles analysed. However, a weak association between exposure to formaldehyde and neoplastic pathologies was seen; 60% of the studies analysed did not report valid evidence to support the association.

It is recommended that the WHO guidelines regarding formaldehyde exposure thresholds are followed and adhered to. Formaldehyde exposure prevention programmes, based on ventilation in the workplace and environmental monitoring to control the concentration of formaldehyde in the atmosphere, are recommended.

Author statements

Ethical approval

Not required as this is an umbrella review.

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Competing interests

The authors declare there are no competing interests.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2023.03.009.

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Short Communication

Risk factors of post-COVID-19 conditions attributed to COVID-19 disease in people aged ≥50 years in Europe and Israel

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ABSTRACT

Objectives: High age, male sex and pre-existing comorbidities are risk factors for a more severe development of COVID-19, and individuals surviving COVID-19 may experience persistent symptoms afterwards referred to as 'post-COVID-19 condition', which represents a range of symptoms after recovering from COVID-19. This study aims at identifying risk factors of post-COVID-19 conditions among people aged ≥50 years.

Study design: We conducted a cross-sectional study based on data from the Survey of Health, Ageing and Retirement in Europe.

Methods: A multiple logistic regression model was used to investigate age, sex, education, comorbidities, smoking, body mass index, and COVID-19 hospitalisation as risk factors of post-COVID-19 condition.

Results: Participants aged ≥70 years (odds ratio [OR] 1.61) with medium (OR 2.38) and lower (OR 2.14) educational levels have a higher risk of post-COVID-19 conditions. In addition, when considering the severity of the COVID-19 disease, those who were hospitalised due to COVID-19 had a 26 times higher risk of post-COVID-19 conditions compared with those who were only tested positive (OR 25.9).

Conclusions: This study supports that health inequalities exist across educational levels with respect to post-COVID-19 conditions, although misclassification may be more common among lower educated participants. The results suggest that policy makers should increase educational interventions towards increasing health literacy.

Key points

- This study examines the risk factors of post-COVID-19 conditions among Europeans aged ≥50 years who tested positive for COVID-19.
- Higher age, low and medium educational level and prior COVID-19–related hospitalisation are risk factors of post-COVID-19 conditions.
- This study suggests policy makers to increase their focus on educational interventions towards increasing health literacy.

Introduction

By fall 2022, the COVID-19 pandemic has been present for more than 2 years, and repercussions of COVID-19 may well be observed. Although COVID-19 strikes at all ages, older people are at increased risk of a critical course of disease, as are people with pre-existing comorbidities.[1] Following COVID-19 disease, lingering symptoms lasting from weeks to months may be experienced. The World Health Organisation has recently coined this as 'post-COVID-19 condition', defined as a condition that "occurs in individuals with a history of probable or confirmed SARS-CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms that last for at least 2 months and cannot be explained by an alternative diagnosis."[2]

Studies describing the risk factors of post-COVID-19 health conditions are limited and show conflicting results, but increasing age, female gender, multimorbidity, high body mass index (BMI),

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lower educational level, having several symptoms during COVID-19 infection, and a more severe acute phase of COVID-19 disease, have all been associated with post-COVID-19 condition.[3,4] Full recovery from COVID-19 is important to keep people's work capacity, productivity, and ability to return to normal everyday activities, and thus, risk factors of post-COVID-19 must be explored. To our knowledge, no previous studies have explored the possible risk factors in a large population-based sample of middle-aged and older adults comparing several countries. Thus, the aim of the study was to investigate risk factors of post-COVID-19 conditions among people aged ≥50 years within 27 European countries and Israel.

Methods

We used data from the second wave of the Survey of Health, Ageing and Retirement in Europe (SHARE) COVID-19 survey (SCS2) conducted from June to August 2021.[5] Participants, who had tested positive with COVID-19 (Supplementary figure F1), were asked, "*Have you experienced any long-term or lingering effects that you attribute to your Covid Illness*?" with the following answer options: 'fatigue', 'cough, congestion, shortness of breath', 'loss of taste or smell', 'headache', 'body aches, joint pain', 'chest or abdominal pain', 'diarrhoea, nausea', 'confusion', and 'other'. Based on this question, an outcome variable was created and dichotomised, indicating whether the respondents had 'no symptoms' or 'one or more'. The following variables were selected as the primary potential risk factors for post-COVID-19 conditions: age (50–69 and ≥70 years), sex (male, female), educational level (according to the International Standardized Classification of Education [ISCED] classified into lower [ISCED groups 0–2], medium [ISCED groups 3–4] and higher [ISCED groups 5–6]), comorbidity ('no diseases', 'one or two diseases', and 'three or more diseases'), smoking ('not smoking', 'smoking now', 'previous smoker'), BMI ('normal weight' (BMI ≥18.5 and <25 kg/m^2), 'underweight' (BMI <18.5 kg/m^2), 'overweight' (BMI ≥25 and <30 kg/m^2) and 'obese' (BMI≥ 30 kg/m^2) and a COVID-19 hospitalisation variable indicating if respondents have been hospitalised due to COVID-19 ('yes' or 'no') and serve as a proxy of the severity of the COVID-19 disease. Moreover, the variable 'country', representing the 28 SHARE countries, was included (Germany, The Netherlands, Belgium, Luxembourg, Switzerland, Austria, France, Spain, Portugal, Malta, Italy, Greece, Cyprus, Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Croatia, Romania, Bulgaria, Denmark, Sweden, Finland, and Israel; Supplementary Table S2). Age, sex, diseases, and COVID-19 hospitalisation were drawn from SCS2, and all other variables were drawn from SHARE wave 8 (conducted in 2020)[6] or the latest wave possible.

Multiple logistic regression models were used to study the risk factors of post-COVID-19 conditions, and the analyses were performed in three steps. First, we included age, gender, education, comorbidity, smoking and BMI (model 1); second, we added a 'country' variable (model 2); and finally, we included the 'COVID-19-hospitalisation' variable (model 3). In all analyses, the cross-sectional individual weights supplied by SHARE were applied to yield a representative sample.

Results

Of all SCS2 participants aged ≥50 years (n = 49,044), 6.5% (n = 3156) reported having tested positive for COVID-19 and were thus included in the final analysis (supplementary figure F1). In the final sample, 42.4% were aged ≥70 years, and 61.6% were females. The proportion of people with a high educational level was 19.2%, 45.1% with a medium level, and 30.4% had a lower educational level (10% were missing). Among the respondents, 19.4% had three or more comorbidities and 24.1% had none, 39.1% were overweight, and 28.4% had a normal BMI. Only 7.9% reported to be smokers, and 16.4% were hospitalised due to COVID-19 disease (Supplementary Table S3).

Of those who tested positive, almost one-quarter (23.5%) reported at least one post-COVID-19 condition, the most common being 'fatigue' (18.8%), followed by 'cough, congestion or shortness of breath' (13.5%) and 'body aches or joint pain' (13.2%; Supplementary Table S4). In the crude analysis, respondents with higher age (≥70 years), medium or low education, multimorbidity, and obesity were at higher risk of post-COVID-19 conditions. However, in the adjusted model (model 1), only older participants (≥70 years; odds ratio [OR] 1.58, 95% confidence interval [CI] 1.06–2.34), and those with a medium (OR 2.46, 95% CI 1.46–4.16) or low education (OR 2.42, 95% CI 1.37–4.25) had a higher risk of post-COVID-19 condition. When adding the country variable to the model (model 2), the risk persisted for those aged ≥70 years (OR 1.61, 95% CI 1.08–2.41), with a medium (OR 2.38, 95% CI 1.39–4.09) or lower (OR 2.14, 95% CI 1.18–3.86) educational level, but the effect attenuated. In addition, when considering the severity of the COVID-19 disease (model 3), those who were hospitalised due to COVID-19 had a 26 times higher risk of post-COVID-19 conditions compared with those who were not hospitalised (OR 25.9, 95% CI 15.64–42.79), and the effect of educational level persisted (medium (OR 2.69, 95% CI 1.48–4.89), lower (OR 2.30, 95% CI 1.22–4.35; Table 1). Sex, comorbidity, BMI, and smoking did not show any association with post-COVID-19 conditions.

Discussion

Post-COVID-19 conditions are common among COVID-19–infected people aged ≥50 years living in the 28 SHARE countries and affects, in particular, older people and those with lower educational level. The association to lower educational level has not been described previously in a European population. However, educational attainment is a social determinant of health, as well as a predictor of the severity of COVID-19 disease.[7] Low educational level is also associated with low health literacy,[8] that is, the ability to reflect upon one's illness and understand how to distinguish between symptoms from chronic disease and symptoms related to COVID-19, and poorer health literacy may explain an overreporting of symptoms.

Not only is increasing age associated with COVID-19 disease severity,[1] but it is also associated with higher risk of post-COVID-19 conditions,[4] and in line with our findings. This may be explained by an age-associated adverse immunological response, as specific cell changes persist longer in older compared with younger individuals,[9] and therefore, the symptoms may be more persistent.

The most salient predictor of post-COVID-19 conditions in our study was the COVID-19 hospitalisation, which may represent the severity of the COVID-19 disease and is in keeping with other studies.[4] However, as intensive treatment during hospital stay can cause similar symptoms,[10] it may be difficult to determine if the symptoms are attributed to the in-hospital treatment, COVID-19, or a combination.

The strength of this study was the large and representative sample of 28 countries using standardised methods for data collection. Also, this study comprised both hospitalised and non-hospitalised participants. However, it is a weakness that SHARE did not collect information on the duration of the post-COVID-19 symptoms to account for the extent of the post-COVID-19 condition. A time frame for long-term or lingering symptoms would have improved the comparability across individuals. In general, we cannot exclude residual confounding; for instance, both hospitalisations and post-COVID-19 conditions may be correlated with

Table 1
The risk of having post-COVID-19 condition.

Variables	Crude		Model 1[a]		Model 2[a + b]		Model 3[a + b + c]	
	OR	95% CI	OR	95% CI	OR	95% CI	OR	95% CI
Age								
50–69	—		—		—		—	
≥70	1.57*	1.05–2.35	1.58*	1.06–2.34	1.61*	1.08–2.41	1.07	0.64–1.80
Sex								
Male	—		—		—		—	
Female	0.98	0.58–1.64	1.14	0.76–1.72	1.18	0.79–1.76	1.31	0.81–2.13
Education								
High	—		—		—		—	
Medium	3.13***	1.77–5.56	2.46***	1.46–4.16	2.38**	1.39–4.09	2.69***	1.48–4.89
Low	3.43***	1.96–6.01	2.42**	1.37–4.25	2.14*	1.18–3.86	2.30**	1.22–4.35
Comorbidity								
0	—		—		—		—	
1–2	1.68	0.93–3.01	1.28	0.73–2.25	1.23	0.71–2.12	0.99	0.58–1.70
≥3	3.40**	1.43–8.08	1.75	0.89–3.46	1.76	0.92–3.37	1.74	0.82–3.67
Smoking								
Not smoking	—		—		—		—	
Previous smoker	1.16	0.75–1.81	1.11	0.74–1.66	1.11	0.74–1.67	1.07	0.64–1.78
Smoker	2.10	0.92–4.77	2.20	0.97–4.98	2.25	0.97–5.18	1.68	0.72–3.94
BMI								
Normal	—		—		—		—	
Underweight	0.28	0.04–1.88	0.27	0.04–1.76	0.23	0.03–1.67	0.35	0.05–2.64
Overweight	1.15	0.68–1.93	1.18	0.76–1.83	1.22	0.78–1.91	1.14	0.69–1.88
Obese	1.86**	1.17–2.94	1.59	0.98–2.59	1.61	0.98–2.67	1.31	0.69–2.46
COVID-19 hospitalisation								
No							Ref	
Yes							25.9***	15.64–42.79
Pseudo R^2			0.059		0.081		0.274	
Observations			2817		2817		2817	

BMI, body mass index; CI, confidence interval; OR, odds ratio.
a: adjusted for age, sex, education, comorbidity, smoking, BMI; b: adjusted for country (Germany used as reference); c: adjusted for COVID-19 hospitalisation.
***$P < 0.001$, **$P < 0.01$, *$PP < 0.05$.

vaccination status. Finally, as a self-reported questionnaire, the post-COVID-19 conditions may be over- or under-reported due to information bias.

Conclusion

The results indicate that lower educational level, higher age, and prior hospitalisation for COVID-19 disease increase the risk of post-COVID-19 conditions. Although biological mechanisms may explain the adverse effects of higher age and disease severity, the effect of a lower educational level for post-COVID-19 conditions is more likely explained by lower health literacy. In conclusion, these findings have implications for public policies in Europe and Israel, as we shed light on the social inequalities in health, which still exist at large. We encourage policy makers to increase their focus on educational interventions and implement programmes and policies to increase health literacy and hereby reduce inequalities in health.

Author statements

Ethical approval

None required.

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Competing interests

None declared.

Data source

This article uses data from SHARE Waves 1, 2, 3, 4, 5, 6, 7, 8 and 9 (DOIs: 10.6103/SHARE.w1.800, 10.6103/SHARE.w2.800, 10.6103/SHARE.w3.800, 10.6103/SHARE.w4.800, 10.6103/SHARE.w5.800, 10.6103/SHARE.w6.800, 10.6103/SHARE.w7.800, 10.6103/SHARE.w8.800, 10.6103/SHARE.w8ca.800, 10.6103/SHARE.w9ca800), see Börsch-Supan et al. (2013) for methodological details.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2022.09.017.

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Themed Paper – Original Research

Science communication in the media and human mobility during the COVID-19 pandemic: a time series and content analysis

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ABSTRACT

Objectives: The relationship between human mobility and nature of science (NOS) salience in the UK news media was examined.
Study design: This is a mixed-method study.
Methods: A time series NOS salience data set was established from the content analysis of 1520 news articles related to non-pharmaceutical interventions of COVID-19. Data were taken from articles published between November 2021 and February 2022, which correlates with period of the change from pandemic to endemic status. Vector autoregressive model fitting with human mobility took place.
Results: The findings suggest that it was not the number of COVID-19 news articles nor the actual number of cases/deaths, but the specific NOS content that was associated with mobility change during the pandemic. Data indicate a Granger causal negative direction ($P < 0.1$) for the effect of the NOS salience represented in the news media on mobility in parks, as well as the effect of scientific practice, scientific knowledge and professional activities communicated in news media on recreational activities and grocery shopping. NOS salience was not associated with the mobility for transit, work or residential locations ($P > 0.1$).
Conclusions: The findings of the study suggest that the ways in which the news media discuss epidemics can influence changes in human mobility. It is therefore essential that public health communicators emphasise the basis of scientific evidence to eliminate potential media bias in health and science communication for the promotion of public health policy. The present study approach, which combines time series and content analysis and uses an interdisciplinary lens from science communication, could also be adopted to other interdisciplinary health-related topics.

Introduction

Non-pharmaceutical interventions (NPIs), such as travel restrictions, have been the core of COVID-19 policies around the globe.[1] Individual efforts to fight the epidemic were unprecedented during this crisis. 'Responsible transport' policies,[2] which emphasise the collective efforts to mitigate the spread of epidemics, reaffirm the importance of individual responsibilities. In this regard, risk communication is key to engaging with the public on NPIs, as unbiased communication promotes acceptance, compliance and policy support. Mass media, such as newspapers, provide a medium to reach a large audience through mass communication, which can have great influence on not only the general public but also the government and transport operators.[3–5]

While pandemics qualify as a form of health crisis,[6] individuals are neither prepared nor possess knowledge of how to deal with such situations.[7] In addition, to support the guidance from experts and governments, information must be disseminated to mobilise the public. Perceivably useful and trustworthy information is usually based on scientific facts.[8] In the case of a health crisis, one of the objectives of science communication is to raise public awareness of the new aspects of scientific evidence, so that they can adhere to preventive measures.[9,10]

This article aims to contribute to the public health literature by focusing on the scientific aspect of risk communication and its relationship with the public mobility response. In particular, this study focuses on the representation of science from a meta-perspective, often referred to as 'nature of science' (NOS), in risk

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and health communication by defining science as a cognitive-epistemic and social-institutional system.[11–14] NOS refers to different aspects of science. It is a meta-level orientation to describe how science works. In other words, NOS provides a bird's-eye view on science, highlighting its various dimensions such as the characteristics of scientific knowledge.[15] The process of generating scientific knowledge behind communicating pandemic health advice involves various NOS categories[11,16] (Table 1). A recent sentiment analysis[17] revealed that the public generally responded positively to scientific method behind COVID-19 vaccines and treatments in tweets. However, it is not yet known whether these NOS aspects influence the tendency of the public to adhere to NPIs.

This study adopted the NOS framework and characterised scientific aspects of health and risk communication by news media. Focusing on NOS enables risk communication researchers to determine whether news media sufficiently articulates how scientific information is generated in risk communication, for example, in the context of the COVID-19 crisis.

Methods

Aims and contributions of the study

This study had two important objectives, as follows: (1) to investigate scientific information represented in UK news articles related to NPIs, such as travel restrictions, and responsiveness of individual actions to curb the spread of disease; and (2) to explore the relationship between the NOS salience in news articles and human mobility responses. A time series NOS salience data set was established from content analysis, and this was combined with a national mobility data set. To the best of the authors' knowledge, to date, there is no research of this nature in the public health literature, and it is important to explore whether the scientific aspect of risk communication is relevant to health policies and practices. In the empirical study, a time series analysis with VAR models was used. This method converted qualitative data from the content analysis into time series big data and is a promising approach for interdisciplinary public health research.

Content analysis

Two coders manually performed a content analysis of 1520 news articles from November 2021 to February 2022. These news articles were surveyed from four major newspaper outlets that cover the range of the political spectrum (The Guardian, The Times, The Telegraph and The Daily Mail).[18] These news articles were obtained from the news database Factiva.[71] The following keywords were used in Factiva: 'COVID-19', 'coronavirus', 'epidemic', 'outbreak', 'pandemic' or 'SARS-CoV-2'.[18] The results returned a total of 7760 news articles. These articles were then screened, and 1520 articles were selected on the basis that they included scientific information in communicating COVID-19 risks related to NPIs.

Next, the NOS framework[11] was used to analyse the inclusion of NOS in communication of COVID-19 NPIs by news media. The NOS framework enables the articulation of different aspects of science in a nuanced manner such that they can be differentiated and clarified. The framework comprises 11 categories that depict how scientific knowledge is formed, certified and affected by different social-institutional factors: aims and values, scientific knowledge, scientific practices, scientific methods, social values, social certification and dissemination, professional activities, scientific ethos, social organisations and interactions, financial systems and political power structures (see Table 1 for definitions). The salience of these NOS categories in newspapers was examined by content analysis. A deductive coding was carried out according to an existing framework[11] that guides the analysis of NOS included in

Table 1
Nature of science categories, aspects of risk communication and excerpts from eligible news articles.[21]

Category	Definition	Excerpts from news articles
Aims and values	The goals that scientific activities desire to fulfil.	"Professor Graham Medley, chair of the Scientific Pandemic Influenza Group on Modelling (SPI-M) … 'Our job is *to lay out a range of possibilities for the future*…'".[22]
Methods	The systematic approaches used to obtain reliable knowledge.	"However, cases are already running far above the numbers being confirmed by PCR testing and the UK is already *relying on other methods*, such as the Office for National Statistics Infection Survey, to assess levels of prevalence".[23]
Practices	A diverse set of activities, such as modelling and analysing data, that help obtain scientific knowledge.	"A travel ban on Britons means "we are successfully putting the brakes on Omicron" while virologists *estimate* the real number of new variant cases is ten times higher than the official figure of 347"[24]
Knowledge	The status of knowledge, such as its certainty and forms (i.e. theories, models).	"It committed the government to examine international public health *models*, learn from best practice, and *reshape* the health system to ensure 'an agile and well-planned response to future epidemics'"[25]
Social certification and dissemination	The peer review process and quality control of scientific processes and products.	"During the audit the firm was being *assessed* by the UK Accreditation Service (UKAS) *to see whether it could be awarded full accreditation* for processing tests".[26]
Scientific ethos	The set of norms, such as scepticism about claims, that scientists engage with	"Reicher's comments risk further undermining confidence in the political *impartiality of scientists* advising UK politicians on coronavirus strategy".[27]
Social values	A set of values agreed by the public in society, such as protecting the vulnerable, fulfilling personal reasonability and restoring the norm by "living with the virus".	"I think it is the wrong course of action for people to take because we have a serious situation we have got to manage and we encourage *everybody to play their part in addressing that*".[28]
Professional activities	Activities for communicating scientific research, such as attending conferences and publishing papers.	"Speaking at a Downing Street *press conference*, Johnson said anyone arriving in England will be asked to take a PCR test".[29]
Social organisations and interactions	The role of institutions, staff unions and research centres in influencing scientific work.	"O'Leary also said that the National Transport Authority (NTA) had not been responsive to *concerns raised by the union* since the onset of the pandemic".[30]
Financial systems	The role of economics in scientific research and economic impact on business.	"Hit hard by pandemic restrictions on travel, *sales in the eight weeks from 6 December were only 57%* of the equivalent in pre-pandemic 2019, the company said in a trading update".[31]
Political power structures	The role of how different political factors, such as politicians, affect scientific work.	"It is also a sign of desperation in Downing Street to avoid a lapse back into more severe restrictions, such as those the *prime minister was forced to introduce* – with great reluctance – last Christmas".[32]

news articles.[19] Initially, excerpts from COVID-19 news articles published in four news outlets corresponding to each NOS category were extracted by the first and second authors. To mark an instance of NOS, the excerpt should have keywords or phrases mentioning how scientific and health information in the crisis was obtained, for example, how the Prime Minster shapes public scientific advice during the COVID-19 pandemic. The first and second authors discussed whether these excerpts aligned with a specific NOS category, as well as refining the definitions of each NOS category based on the chosen excerpts. Coding was applied to each article, and more than one NOS category could be applied to each article (see Table 1 for examples of excerpts from news articles). In total, 10% of the articles were randomly selected and analysed by both coders (i.e. the first and second authors). Intercoder reliability, reflecting agreement of coding between both authors, was calculated.[19] The final Cohen's kappa coefficient was 0.81, which indicated an acceptable threshold of reliability.[20] The remaining news articles were analysed by both coders independently.

To operationalise content analysis in the time series analysis, the salience of an NOS category was defined as the proportion of codes addressing a specific NOS category per day. The proportion was calculated by dividing the number of codes addressing a specific NOS category by the number of codes on that day. The cumulative daily proportion of the NOS salience always summed to 1. Table 2 presents the mean number of articles addressing an NOS category each day.

Time series analysis

The association of the percentage of daily NOS salience in the UK national media on national-level mobility indicators was examined. Human mobility data were obtained from the community mobility report developed by Google,[33] which has been used in many empirical studies in the literature.[34–36] The data set shows how visits and length of stay at different location categories, including retail and recreation (e.g. restaurants, cafes, shopping centres), grocery and pharmacy (e.g. grocery supermarkets), parks (e.g. parks and public beaches), transit (e.g. public transport hubs), workplaces and residential areas, change compared with a baseline (i.e. the median value for the corresponding day of the week during the 5-week period from 3 January to 6 February 2020). COVID-19 situation data were obtained from the Oxford COVID-19 Government Response Tracker and details can be found in the study by Hale et al.[37] Table 2 presents the descriptive statistic of mobility and COVID-19 situation data.

First, the augmented Dickey–Fuller test (ADF) was used to determine the stationarity of variables and their order of integration. Dickey and Fuller[38] tests determine the presence of a unit root (then, the series can be considered as non-stationary) or not (the series is stationary). The Dickey–Fuller test is testing if $\gamma = 0$ in this model of the data:

$$\Delta y_t = \alpha + \beta t + \gamma y_{t-1} + \delta_1 \Delta y_{t-1} + \delta_2 \Delta y_{t-2} + \ldots$$

where y_t is the time series data. A linear regression of Δy_t against t and y_{t-1} was conducted for testing if γ is different from 0. If $\gamma = 0$, then there was a random walk process, otherwise there was a stationary process.

The null hypothesis for both tests was that the data were non-stationary. The analysis started by applying a unit root test on the variables included in the data set. As can be seen in Table 2, the null hypothesis that each of the variables contains a unit root was rejected at the 10% critical level, except for 'hospitalisation' and 'stringency'. Analytically, the ADF t-statistics for the first difference of the variables were statistically significant, leading to the rejection of the null hypothesis that the first differences are non-stationary. That is, hospitalisation and stringency were characterised by integration of degree one, whereas all the other variables of interest were stationary.

Table 2
Descriptive statistic and unit root test of mobility, NOS salience and COVID-19 situation data.

Variable	Mean	SD	Minimum	Maximum	ADF (levels)			ADF (first differences)		
					t-stat	Critical values	Stationarity	*t*-stat	Critical values	Stationarity
Mobility (location)										
Recreation	−0.14	0.11	−0.87	0.07	−6.007	−2.889	Yes	–	–	–
Grocery	0.01	0.13	−0.88	0.42	−6.808	−2.889	Yes	–	–	–
Parks	0.08	0.14	−0.49	0.42	−7.444	−2.889	Yes	–	–	–
Transit	−0.33	0.10	−0.81	−0.17	−3.946	−2.889	Yes	–	–	–
Work	−0.27	0.16	−0.78	−0.01	−5.736	−2.889	Yes	–	–	–
Residential	0.08	0.04	0.00	0.21	−5.654	−2.889	Yes	–	–	–
Media										
NOS category										
Aims and values	0.03	0.04	0.00	0.17	−10.197	−2.889	Yes	–	–	–
Methods	0.03	0.03	0.00	0.12	−10.920	−2.889	Yes	–	–	–
Practices	0.13	0.06	0.00	0.35	−8.908	−2.889	Yes	–	–	–
Knowledge	0.09	0.06	0.00	0.38	−9.768	−2.889	Yes	–	–	–
Social certification and dissemination	0.03	0.03	0.00	0.17	−9.358	−2.889	Yes	–	–	–
Scientific ethos	0.01	0.02	0.00	0.14	−10.291	−2.889	Yes	–	–	–
Social values	0.12	0.06	0.00	0.29	−9.237	−2.889	Yes	–	–	–
Professional activities	0.10	0.06	0.00	0.29	−10.756	−2.889	Yes	–	–	–
Social organisations and interactions	0.05	0.04	0.00	0.20	−9.994	−2.889	Yes	–	–	–
Financial systems	0.10	0.07	0.00	0.38	−9.401	−2.889	Yes	–	–	–
Political power structures	0.31	0.07	0.14	0.50	−8.467	−2.889	Yes	–	–	–
Daily number of COVID-19 news articles	12.6	6.21	2	32	−6.051	−2.889	Yes	–	–	–
COVID-19 situation										
Cases	82435.62	83359.83	29843	847371	−8.166	−2.889	Yes	–	–	–
Deaths	174.74	137.27	3	1121	−7.470	−2.889	Yes	–	–	–
Hospitalisation	11857.54	4175.40	7251	20062	−0.605	−2.889	No	−4.768	−2.889	Yes
Stringency	44.13	5.05	23.15	48.61	2.062	−2.889	No	−8.162	−2.889	Yes

ADF, augmented Dickey–Fuller; NOS, Nature of science; SD, standard deviation.

If the series presents the same order of integration, a risk of cointegration between variables was possible. Cointegration tests must be undertaken. The existence of a possible cointegration relationship implies that variables must be non-stationary. The Johansen[39] cointegration tests were used to determine the number of cointegration relationships. These tests require the selection of the optimum lags of the VAR model, which were determined with the likelihood ratio, final prediction error criterion, Akaike information criterion, Hannan-Quinn information criterion and Schwarz information criterion. Lag-order selection statistics for VARs were obtained using the 'varsoc' function in Stata/SE 17.0. Then, the lag length (p) was selected through the estimation of an unconditional VAR model (Table 3). Equations of the test are detailed in a study by Khan and Khan.[40]

Results

Mobility at all locations was generally stable throughout the study period, except during the omicron outbreak from mid-December 2021 to mid-January 2022. Residential mobility maintained a slightly higher level than at baseline, whereas mobility at the other locations declined rapidly after the outbreak. Locations categorised as retail and recreation, grocery and pharmacy, and parks sharply increased after a one week time frame, whereas locations of transit and workplace gradually returned to the pre-outbreak levels. From the VAR model, it can be seen that mobility in some locations was associated with mobility in other locations. Transit, being a fundamental location for transport services, was positively associated with all locations, except parks. These results support the usefulness of mobility data in the case of the United Kingdom.

Next, the NOS salience in COVID-19–related news (Table 2) was examined. The political and power structures was the most prominent NOS category in risk communication in COVID-19 news (mean = 0.31); the practices category was the second most prominent (mean = 0.13); and social values was the third most prominent category (mean = 0.12). Scientific ethos was the least prominent among all 11 NOS categories (mean = 0.01). These results suggested that while a great deal of emphasis was placed on the politics in news media whereas the ethos of science, in terms of scepticism and universalism, was overlooked.

Finally, relationships between mobility and the NOS salience were examined. Granger causality tests performed on the VAR models showed that there was instantaneous causality between the media frames and mobility in almost every model for the containment and social frames and Granger causality in some. Table 4 details the coefficients in six models. A Granger causal direction ($P < 0.1$) represents an effect of the NOS salience in news media on mobility and can be seen in public parks, as well as the effect of scientific practice, knowledge and professional activities represented in news media on recreation and grocery. The directions of association were all negative, meaning that higher NOS salience represented in news media contributed to decreased mobility. NOS salience communicated in news media was not associated with mobility at transit, work or residential locations ($P > 0.1$).

Fig. S1 in the supplementary material shows a graphical representation of human mobility, NOS salience and COVID-19 situation indicators over study period.

Table 3
Lag selection.

Lag	FPE	AIC	HQIC	SBIC
0	3.00E-23	7.73824	7.94505	8.24796
1	6.80E-25	3.84369	8.39348	15.0575
2	8.50E-25	3.30045	12.1932	25.2183
3	2.10E-25	−0.508144	12.7276	32.1138
4	1.60E-27	−11.9945	5.58422	31.3315
5	7.e−244[a]	−536.005[a]	−514.084[a]	−481.975[a]

FPE, final prediction error criterion; AIC, Akaike information criterion; HQIC, Hannan-Quinn information criterion; SBIC, Schwarz information criterion.
[a] Optimum lags.

Discussion

This empirical study examined the relationship between NOS salience in news media and public mobility. The results suggest that it is not the number of COVID-19 news articles,[41,42] but it was the amount of NOS content in news media that was associated with pandemic mobility. Specifically, scientific practices and knowledge, which refer to the scientific activities that lead to the generation of scientific knowledge and the sources and forms of knowledge in risk communication, respectively, were associated with decreased time spent in recreation, grocery and park locations, given that the two variables are complementary and therefore tend to be opposite in direction. In other words, it was not the exact number of COVID-19 cases, but the salience of scientific practices (e.g. analysing COVID-19 case data by the government) and knowledge (e.g. uncertainty in trends of COVID-19 cases) related to the COVID-19 situation reported in the media that impacted mobility changes (i.e. decrease in overall mobility and an increase in time spent at home). Meanwhile, the NOS (represented by news media) was highly associated with decreased time spent in park areas. However, the impacts of mobility at transit, work and residence locations were not significantly associated with NOS salience. This could potentially be explained from the transport perspective, in that transit and work are essential trips unless the government implement social distancing practices (e.g. work from home). The findings for the residence location tended to be in the opposite direction to transit and work locations. Recreation, grocery and park locations can be deemed as relatively optional (i.e. non-essential trips). Although most associations were instantaneous (making it impossible to determine the causal direction of effects), the Granger causality tests suggested directional effects of NOS salience in news media on mobility in public parks. The data suggested that it was more likely that the media influenced mobility and not *vice versa*.

Implications

In the 'opening-up' period during the COVID-19 crisis, travel behaviours were mainly driven by public perception of viral risks and uncertainties. Uncertainties perceived by people led them to actively practise social distancing (e.g. to avoid gathering in public areas such as grocery supermarkets, transit areas and workplaces) and shift to more open areas, such as parks.[43–46] As public transport was unjustifiably stigmatised by media, authorities and citizens,[47,48] passengers who were concerned about the risk of infection tended to drive more and avoid public transport,[49,50] which continues in the post-pandemic period.[51]

News media is the major source where the public obtains risk information in the COVID-19 pandemic[52] to make informed decisions. According to risk communication models,[53,54] the public should be informed about risks (health and social) and responses (individual and organisational). Owing to a flow of misinformation in mass media, news plays a role in alerting the public to danger and reassuring the public in the trustworthiness of scientific information.[55] However, risk communication in news media often lacks robust information on the sources and reliability of scientific knowledge.[56,57] In the healthcare pandemic crisis, news media

Table 4
VAR model coefficients.

Independent variable	Dependent variable											
	Recreation		Grocery		Parks		Transit		Work		Residential	
	Coefficient	Standard error	Coefficient	Standard error	Coefficient	Standard error	Coefficient	Standard error	Coefficient	Standard error	Coefficient	Standard error
Mobility (location)												
Recreation	−0.89[a]	0.30	−1.14[a]	0.38	−0.62	0.38	−0.70[a]	0.23	−0.68	0.45	0.01	0.12
Grocery	0.38[b]	0.20	0.30	0.26	0.32	0.26	0.02	0.16	−0.32	0.31	0.12	0.08
Parks	−0.15[b]	0.09	−0.04	0.11	−0.14	0.12	0.08	0.07	0.36[a]	0.14	−0.07[c]	0.04
Transit	1.25[a]	0.34	1.24[a]	0.42	0.34	0.43	1.58[a]	0.26	1.98[a]	0.51	−0.41[c]	0.13
Work	−0.35[b]	0.19	0.01	0.24	−0.05	0.24	−0.16	0.15	0.31	0.29	0.00	0.08
Residential	−0.27	0.84	0.44	1.06	0.17	1.06	1.24[b]	0.66	3.96[c]	1.27	−0.61[b]	0.33
Media												
NOS category												
Aims and values	−0.66	0.47	−0.60	0.59	−2.03[a]	0.59	−0.09	0.36	0.48	0.70	−0.06	0.18
Methods	−0.47	0.46	−0.36	0.57	−1.23[c]	0.58	−0.07	0.36	0.40	0.69	−0.06	0.18
Practices	−0.98[c]	0.42	−0.95[c]	0.52	−1.57[a]	0.53	−0.31	0.33	0.30	0.63	−0.07	0.16
Knowledge	−0.70[b]	0.42	−0.73	0.53	−1.47[a]	0.53	−0.12	0.33	0.56	0.63	−0.09	0.16
Social certification	−0.57	0.53	−0.58	0.67	−0.88	0.67	−0.15	0.41	−0.05	0.80	0.01	0.21
Social values	−0.62	0.43	−0.70	0.54	−1.14[c]	0.54	0.00	0.33	0.50	0.65	−0.11	0.17
Professional activities	−0.77[b]	0.46	−0.83	0.58	−1.70[a]	0.58	−0.08	0.36	0.62	0.69	−0.13	0.18
Social organisations	−0.68	0.48	−0.87	0.61	−1.52[c]	0.61	0.00	0.38	0.68	0.73	−0.18	0.19
Financial systems	−0.66	0.41	−0.73	0.51	−1.59[a]	0.52	−0.01	0.32	0.74	0.62	−0.13	0.16
Political power structures	−0.68	0.41	−0.73	0.52	−1.54[a]	0.52	−0.08	0.32	0.62	0.62	−0.14	0.16
No. of COVID-19 news articles	0.00	0.00	0.00[b]	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
COVID-19 situation												
Cases	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Deaths	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Hospitalisations	0.00	0.00	0.00	0.00	0.00[b]	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Stringency	0.00	0.01	0.00	0.01	0.03[c]	0.01	0.00	0.01	−0.02	0.01	0.00	0.00
Constant	0.77[b]	0.40	0.94[b]	0.50	1.59[c]	0.51	0.05	0.31	−0.52	0.60	0.11	0.16

Scientific ethos omitted because of collinearity. The cumulative daily proportion of the NOS salience always sums to 1 and thus one category could not be put together in the model due to multicollinearity.
NOS, nature of science; VAR, vector autoregressive model.
[a] Significant at the 0.01 level.
[b] Significant at the 0.1 level.
[c] Significant at the 0.05 level.

often uses sensationalism to heighten public concerns.[58] For example, the scientific frame focused mainly on the biology of the virus and health impacts (e.g. symptoms and case/deaths) but lacked practical advice for individuals and communities.[59] This suggests that the media did not provide the public with the necessary information to make informed decisions.

In addition, social media platforms provide alternative means for public engagement in scientific communication during pandemic crises.[17,60] However, this could lead to the unintentional spread of misinformation.[61] Poor adherence, mistrust and public fear are factors that threaten the effectiveness of the public health measures to prevent the spread of diseases.[62] The present study, by identifying certain types of NOS salience in news media that were associated with changes in public mobility, can help the government and media publishers understand how scientific content in the media mediates community responses in future health crises. To help individuals make informed decisions and minimise the effects of the pandemic, it is important to disseminate scientific content in (social) media to prevent further spread of the virus in an effective and sustainable manner.[63]

Limitations

The present study was subject to several limitations. First, the study was limited by a lack of information on the distribution and size of the mobility data collected by Google. Furthermore, the data were only available for Android users whose location history had been turned on. Despite these constraints, multiple scholars have found that the data can be useful in predicting social phenomena.[34–36] In addition, although the Granger test results suggested that directionality was applicable for some variables, causality should be taken with a caution, as this study did not directly examine how exposure to news articles impacted individuals' behaviours. In addition, the manual coding of news articles might be influenced by the background and expertise of the coders. As NOS is a meta-characterisation of how scientific information was obtained in communicating public health crises, using a machine learning technique for processing news articles might not accurately capture holistic aspects of scientific works. This is counterbalanced by calculating intercoder reliability and providing an explanatory and transparent procedure of coding.

The study findings demonstrate the need to cover epidemics in responsible ways that emphasise how scientific information is generated and how risk information is shared. Even after the effects of COVID-19 have diminished, the public remain concerned and fear for their safety on public transport.[51] To restore public trust in public transport, the government and general practitioners need to promote and introduce specific measures,[64–68] possibly starting with the justification of sources and forms of scientific information in the news media.

Future research could further examine the geographical disparities and exposure to different media platforms within the same country or among different countries. The present study approach combines time series and content analysis, as well as using an interdisciplinary lens from science communication. This approach can be adopted to other interdisciplinary public health topics, such as air pollution in relation to climate change and physical activity in relation to emerging transport innovations, such as the e-scooter.

Finally, using a nuanced approach to the characterisation of science in health and risk communication, namely, through a robust framework on NOS, researchers may potentially uncover what aspects of science in health and risk communication in news media need to be clarified and emphasised for enhanced mobility response to crises such as the COVID-19 pandemic.[69,70]

Author statements

Ethical approval

Not applicable.

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Competing interests

The authors declare that they have no competing interests.

Author contributions

H.-Y.C. contributed to conceptualisation, data curation, methodology, software, visualisation and writing, reviewing and editing. K.K.C.C. contributed to conceptualisation, data curation, methodology, writing, reviewing and editing. S.E. contributed to conceptualisation, supervision, and review and editing.

Appendix A. Supplementary data

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